SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

1. Purchase Authority: Public Law 92-218 as amended

2. **Request For Proposal (RFP) Number**:	3. **Issue Date**:	4. **Just In Time**:	5. **Set Aside**:
RFP-NHLBI-HC-06-02	8/16/2005	**[ ]** NO **[X]** YES See Part IV Section L	**[X]** NO **[ ]** YES See Part IV Section L

6. TITLE: Hispanic Community Health Study - Field Centers

7. ISSUED BY:	8. SUBMIT OFFERS TO:
Contract Operations Branch National Heart, Lung, and Blood Institute National Institutes of Health 6701 ROCKLEDGE DRIVE MSC 7902 BETHESDA MD 20892-7902	See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.

9. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1 until **4:00 p.m. local time on 12/1/05.** Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment No. 11, entitled, "Proposal Summary and Data Record, NIH 2043." **PROPOSAL INTENT FORM DUE 11/1/2005.**

10. THE OFFICIAL POINT OF RECEIPT FOR THE PURPOSE OF DETERMINING TIMELY DELIVERY IS THE ADDRESS PROVIDED FOR THE REVIEW BRANCH BRANCH AS STATED IN ATTACHMENT 1. IF YOUR PROPOSAL IS NOT RECEIVED BY AT THE PLACE AND TIME SPECIFIED, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH HHSAR CLAUSE 352.215-70, ENTITLED, "LATE PROPOSALS, AND REVISIONS" LOCATED IN SECTION L.1. OF THIS SOLICITATION.

11. Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract. (http://www.ccr.gov)

12. FOR INFORMATION CALL: Kristiane E. Cooper
PHONE: 301-435-0345
COLLECT CALLS WILL NOT BE ACCEPTED.

13. Table of Contents on following page.

13. DETAILED TABLE OF RFP CONTENTS

PART I - THE SCHEDULE

THE CONTRACT SCHEDULE SET FORTH IN SECTIONS B THROUGH H, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS **NOT** AN EXACT REPRESENTATION OF THE PROPOSED CONTRACT DOCUMENT. CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (I.E., THOSE RELATING TO THE ORGANIZATIONAL STRUCTURE [E.G., NON-PROFIT, COMMERCIAL] AND SPECIFIC COST AUTHORIZATIONS UNIQUE TO THE OFFEROR'S PROPOSAL AND REQUIRING CONTRACTING OFFICER PRIOR APPROVAL) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. HOWEVER, THE ENCLOSED CONTRACT SCHEDULE PROVIDES ALL THE NECESSARY INFORMATION FOR THE OFFEROR TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

This contractor will serve as one of up to four Field Centers for the Hispanic Community Healthy Study. The Hispanic Community Health Study is a multicenter epidemiologic study to identify, recruit, examine, and follow up to four community-based cohorts of adults, all of Hispanic origin, of size 4,000 each, ages 18-74. The four cohorts will be majority Cuban, Puerto Rican, Mexican American, and Central American. Distinctive factors hypothesized to influence risk (protective or harmful) to be measured include social, behavioral, occupational and lifestyle factors, and acculturation (e.g., nutrition habits, access to health care, role of family and community, cigarette smoking, sleep behaviors). Measures of obesity, activity, diabetes, lung function, cognitive function, hearing, dental conditions, and cardiovascular risk factors will also be studied.

ARTICLE B.2. PRICES/COSTS

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; and 9) Research Funding.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, Section J, ATTACHMENT 3, attached hereto and made a part of this Solicitation

ARTICLE C.2. REPORTING REQUIREMENTS

a. Technical Progress Reports

In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award.

A Semiannual Progress Report, with the first due 6 months after the effective date of the contract. This report will detail the progress of the entire contract work for the previous 6 months and includes a list of all contract supported staffing for the reporting period, with names, position titles, FTE levels, and type of

work performed. A description of activities including recruitment of participants into the study, examination progress, research proposed and completed.

b. Summary of Salient Results

The Contractor will be required to prepare and submit, with the final report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract. This report will be required on or before the expiration date of the contract.

c. Other Reports

1. Annual Technical Progress Report for Clinical Research Study Populations

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. The contractor shall submit this information in the format indicated in the attachment entitled, "Inclusion Enrollment Report," which is set forth in Section J of this contract. The contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the final report.

The contractor shall submit the report in accordance with ARTICLE F.1. DELIVERIES of this contract.

In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October, 2001 applies. If this contract is for Phase III clinical trials, see II.B of these guidelines. The Guidelines may be found at the following website:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups in the clinical trial protocol as approved by the IRB, and provide a description of the progress in the conduct of these analyses, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the contractor shall include all final analyses of the data on sex/gender and race/ethnicity.

2. Invention Reporting Requirement

All reports and documentation required by [FAR Clause 52.227-11/FAR Clause 52.227-11 (Deviation)/FAR Clause 52.227-13] including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Office of Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040 A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the expiration date of the contract to the Contracting Officer.

The annual utilization report shall be submitted in accordance with ARTICLE F.1. DELIVERIES of this contract. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the expiration date of the contract to the following address:

Contracting Officer
National Institutes of Health
National Heart, Lung, and Blood Institute
Rockledge Building (RLL2)
6701 Rockledge Drive MSC 7902
Bethesda, Maryland 20892 - 7902

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Office of Extramural Inventions and Technology Resources Branch, OPERA, NIH.

SECTION D - PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this SECTION, the Project Officer is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at the National Heart, Lung, and Blood Institute.

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause **52.246-9, Inspection of Research and Development (Short Form)** (April 1984).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in Article C.1. and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

a. The items specified below as described in **SECTION C, ARTICLE C.2.** will be required to be delivered F.O.B. Destination as set forth in FAR Clause 52.247-35, F.O.B. Destination, Within Consignees Premises (April 1984), and in accordance with and by the date(s) specified below and any specifications stated in **SECTION D, PACKAGING, MARKING AND SHIPPING**, of the contract:

Item #	Description	Qty.	Delivery Schedule	
1	Semi-Annual Progress Report	3	Semiannually starting 6 months after contract signing.	Contracting Officer (1) and Project Officer (2)
2	Study data	1	As required by protocol	To the Coordinating Center as specified by the protocol
3	Samples, tapes/disks, images and other data on study subjects	1	2 years after each annual closure	To the Coordinating Center, Labs and Reading Centers as specified by the protocol
4	IRB Approved Consent Corms	2	Annually upon closure	Contracting Officer (1) and Project Officer (1)
5	Recruitment and Contract Reports by Gender	2	6 months prior to start of examinations	Contracting Officer (1) and Project Officer (1)
6	Draft Final Report	3	2 Months before expiration of contract	Contracting Officer (1) and Project Officer (2)
7	Final Report	3	At expiration of contract	Contracting Officer (1) and Project Officer (2)

b. The above items shall be addressed and delivered to:

The items above shall be delivered to the following addresses:

Addressee
Contracting Officer
Contracts Operations Branch, DEA, NHLBI
Two Rockledge Center, Room 6136
6701 Rockledge Drive, MSC 7902
Bethesda, MD 20892-7902

Project Officer
6701 Democracy Blvd.
Room 950, MSC 4874
Bethesda, MD 20892-6401

Coordinating Center
Address: TBD

Laboratory and Reading Centers
Addresses TBD

The specific information will be included in the resultant contract

ARTICLE F.2. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989) with **Alternate I** (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

Any contract awarded from this RFP will contain the following:

ARTICLE G.1. PROJECT OFFICER

The following Project Officer(s) will represent the Government for the purpose of this contract:

[To be specified prior to award]

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Contracting Officer hereby delegates the Project Officer as the Contracting Officer's authorized representative responsible for signing software license agreements issued as a result of this contract.

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in this contract, the following individual(s) is/are considered to be essential to the work being performed hereunder:

NAME TITLE

[To be specified prior to award]]

ARTICLE G.3. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the DHHS Publication (OS) 686, entitled, **Contractor's Guide for Control of Government Property**, (1990) which can be found at:
http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm

ARTICLE G.4. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluations will be prepared annually to coincide with the anniversary date of the contract.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:
http://ocm.od.nih.gov/cdmp/cps_contractor.htm

The registration process requires the contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

Research involving human subjects shall not be conducted under this contract until the protocol developed in Phase I has been approved. Written notice of such approval has been provided by the Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310).

ARTICLE H.2. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. The information below is a summary of the NIH Policy Announcement:

The contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been

coompleted for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

ARTICLE H.3. HUMAN MATERIALS

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.4. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

a. Pursuant to Public Law(s) cited in paragraph b. , below, NIH is prohibited from using appropriated funds to support human embryo research. Contract funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

   Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.5. NEEDLE EXCHANGE

a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.6. PRIVACY ACT

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties.

The Privacy Act System of Records applicable to this project is Number 09-25-0200. This document is incorporated into this contract as Attachment .

ARTICLE H.7. OMB CLEARANCE

In accordance with HHSAR 352.270-7, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Project Officer and the Contracting Officer has issued written approval to proceed.

ARTICLE H.8. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

(1) The Small Business Subcontracting Plan, dated (to be determined at time of award) is attached hereto and made a part of this contract.

(2) The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. Subcontracting Reports

(1) **Subcontracting Report for Individual Contracts, SF-294**

The Contractor shall submit the original and one (1) copy of Subcontracting Report for Individual Contracts, SF-294 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. In addition to the information contained in the General Instructions on the back of this form for Block 17, "Remarks," the Contractor shall provide an explanation **for any category** of small business subcontracting for which there were no dollars reported since the last reporting period.

Regardless of the effective date of this contract, the Report shall be submitted on the following dates for the entire life of this contract:

April 30th
October 30th

The Report shall be sent to the Contracting Officer at following address:

Contracting Officer
Contract Operations Branch
National Heart, Lung, and Blood Institute, NIH
Rockledge, Maryland, Room 6124
Bethesda, Maryland 20892-7902

(2) **Summary Subcontract Report, SF-295**

The Contractor shall submit two (2) copies of Summary Subcontract Report, SF-295 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30th

One copy of this report shall be sent to the Contracting Officer at the address above. One copy of this Report shall be mailed to the Office of Small and Disadvantaged Business Utilization, DHHS at the following addresses:

Office of Small and Disadvantaged Business Utilization

Department of Health and Human Services
Hubert H. Humphrey Bldg., Room 360G
200 Independence Avenue, S.W.
Washington, D.C. 20201

(3) The contractor shall also send an "Information Copy" of the SF-295 to the Cognizant Commercial Representative (CMR) at the address provided by the SBA. The Contractor should call SBA Headquarters in Washington, DC at (202) 690-7235, for the correct address if unknown.

ARTICLE H.9. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to the P.L.(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of the applicable amount shown or the applicable Executive Level for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead and general and administrative expenses (also referred to as "indirect costs" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor. The per year salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.

b. **Public Law No.**	**Fiscal Year**	**Dollar Amount of Salary Limitation***

[Applicable information to be included at award]

c. Payment of direct salaries is limited to the Executive Level I rate which was in effect on the date(s) the expense was incurred.

* For the period 10/1/04 - 12/30/04, the Executive Level I rate is $175,700. Effective January 1, 2005, the Executive Level I rate increased to $180,100 and will remain at that rate until it is revised. See the web site listed below for the Executive Schedule rates of pay:

FOR FY05 EXECUTIVE LEVEL SALARIES EFFECTIVE JANUARY 1, 2005:
http://www.opm.gov/oca/05tables/html/ex.asp
(NOTE: This site shows the CY 05 rates. For previous years, click on "salaries and wages" and then scroll down to the bottom of the page and click on the year to locate the desired Executive Level salary rates).

ARTICLE H.10. ENERGY STAR REQUIREMENTS

Executive Order 13123, "Greening the Government Through Efficient Energy Management" and FAR 23.203 require that when Federal Agencies acquire energy using products, they select, where life-cycle cost-effective, and available, ENERGY STAR® or other energy efficient products.

Unless the Contracting Officer determines otherwise, all energy-using products acquired under this contract must be either an ENERGY STAR® or other energy efficient product designated by the Department of Energy's Federal Energy Management Program (FEMP).

For more information about ENERGY STAR® see http://www.energystar.gov/
For more information about FEMP see http://www.eere.energy.gov/

ARTICLE H.11. PUBLICATION AND PUBLICITY

The contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, under Contract No. .

ARTICLE H.12. PRESS RELEASES

a. Pursuant to Public Law(s) cited in paragraph b., below, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.13. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS** (**1-800-447-8477).** All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.14. ANTI -LOBBYING

a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall only be used for normal and recognized executive-legislative relationships. Contract funds shall not be used, for publicity or propaganda purposes; or for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.

b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

c. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.15. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at : http://ott.od.nih.gov/NewPages/64FR72090.pdf. is intended to help contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

Note: For the purposes of this Article, the terms, "research tools," "research materials," and "research resources" are used interchangeably and have the same meaning.

ARTICLE H.16. SHARING RESEARCH DATA

The contractor's data sharing plan, dated (TBD) is hereby incorporated by reference. The contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.
The data sharing plan submitted by the contractor is acceptable/The contractor's data sharing plan, dated (to be determined at time of award). The contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Privacy Rule at http://www.hhs.gov/ocr/). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

ARTICLE H.17. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

Public accommodations that meet the requirements can be accessed at: http://www.usfa.fema.gov/hotel/index.htm

ARTICLE H.18. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

The Policy requests that beginning May 2, 2005, NIH-funded investigators submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html.

ARTICLE H.19. DATA AND SAFETY MONITORING IN CLINICAL TRIALS AND EPIDEMIOLOGICAL STUDIES

For informational purposes, the contractor is directed to the full text of the NHLBI policies regarding Oberservational Study Monitoring Boards, which may be found at the following web sites:

- Establishing Data and Safety Monitoring Boards and Observational Study Monitoring Boards (http://www.nhlbi.nih.gov/funding/policies/dsmb_est.htm)
- Guidelines for Data Quality Assurance in Clinical Trials and Observational Studies (http://www.nhlbi.nih.gov/funding/policies/dataqual.htm)
- Responsibilities of OSMBs Appointed by the NHLBI (http://www.nhlbi.nih.gov/funding/policies/osmb_inst.htm)

ARTICLE H.20. NHLBI LIMITED ACCESS DATA

The National Heart, Lung, and Blood Institute (NHLBI) has supported collection of data from participants in numerous clinical trials and epidemiologic studies. These well-characterized population samples represent rare and valuable scientific resources. In order to take full advantage of such resources and maximize their research value, it is important that data collected with public funds be made available, under appropriate terms and conditions, to the largest possible number of qualified investigators in a timely manner.

Limited access data will be released under this trial or study. Limited access data refers to trial or study data, with certain deletions and recoding, that are released to requesting institutions and investigators for specific purposes and with certain restrictions and conditions. The contractor shall distribute study data in accordance with NHLBI's Policy for Distribution of Data dated August 2005 and any subsequent revisions. The policy is described at http://www.nhlbi.nih.gov/resources/deca/policy.htm.

Limited access data is a deliverable under the coordinating center contract for this trial or study, as described in Section C. Description/Specification/Work Statement and/or Section F. Deliveries or Performance of the coordinating center contract.

H.21. REVIEW OF MANUSCRIPTS

In order to balance the oversight responsibility of the National Heart, Lung, and Blood Institute (NHLBI) with the authorization provided the contractor by the Rights in Data clause of this contract, the NHLBI has established a process to review manuscripts produced under this contract. Please note that the NHLBI does not require contractors to seek the Institute's approval of manuscripts.

In order to have sufficient time to conduct a meaningful review, please provide to the Institute's Project Officer and Contracting Officer advance notice of intent to submit a manuscript for publication at least 45 days prior to submission to the publisher. The advance notice should briefly describe the plans for publication of the manuscript. Concurrently or as soon as possible following this notice, please provide the manuscript just to the Project Officer.

Any comments from the NHLBI will be provided in writing within 15 days after receipt of the manuscript by the Project Officer. Comments expressed by the NHLBI about the manuscript shall not be a cause for action under the Disputes clause of the contract by either NHLBI or the contractor, since the NHLBI does not approve manuscripts and draft manuscripts are not contract deliverables.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING **ARTICLE I.1 GENERAL CLAUSE LISTING(S)** WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP:

General Clauses for a Cost-Reimbursement Research and Development Contract

General Clauses for a Cost-Reimbursement Contract with Educational Institutions

General Clauses for a Cost-Reimbursement Contract with Non-Profit Organizations Other Than Educational Institutions

The complete listing of these clauses may be accessed at:

http://rcb.cancer.gov/rcb-internet/appl/general-clauses/clauses.jsp

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following clause(s) will be made part of the resultant contract:

FAR Clause **52.232-20, Limitation Of Cost** (April 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation Of Funds** (April 1984) is substituted therefor. ***[NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]***

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

(1) FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (October 2004).

"(c) Waiver of evaluation preference.....

[ ] Offeror elects to waive the evaluation preference."

(2) FAR Clause **52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting** (October 1999).

(3) FAR Clause **52.227-14, Rights in Data - General** (June 1987).

(4) FAR Clause **52.239-1, Privacy or Security Safeguards** (August 1996).

(5) FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).

(6) FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), **Alternate V** (April 1984).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

(1) HHSAR Clause **352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities** (January 2001).

(2) HHSAR Clause **352.270-8, Protection of Human Subjects** (March 2005).

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

(1) **NIH (RC)-7, Procurement of Certain Equipment** (April 1984) (OMB Bulletin 81-16).

(2) **NIH(RC)-11, Research Patient Care Costs** (4/1/84).

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

a. FAR Clause **52.222-39, Notification Of Employee Rights Concerning Payment Of Union Dues Or Fees** (December 2004)

(a) Definition. As used in this clause--

United States means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.

(b) Except as provided in paragraph (e) of this clause, during the term of this contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union membership and payment of union dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to employees are customarily posted. The notice shall include the following information (except that the information pertaining to National Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).

Notice to Employees

Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an employer to enter into a union-security agreement requiring employees to pay uniform periodic dues and initiation fees. However, employees who are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.

If you do not want to pay that portion of dues or fees used to support activities not related to collective bargaining, contract administration, or grievance adjustment, you are entitled to an appropriate reduction in your payment. If you believe that you have been required to pay dues or fees used in part to support activities not related to collective bargaining, contract administration, or grievance adjustment, you may be entitled to a refund and to an appropriate reduction in future payments.

For further information concerning your rights, you may wish to contact the National Labor Relations Board (NLRB) either at one of its Regional offices or at the following address or toll free number:

National Labor Relations Board
Division of Information
1099 14th Street, N.W.
Washington, DC 20570
1-866-667-6572
1-866-316-6572 (TTY)

To locate the nearest NLRB office, see NLRB's website at http://www.nlrb.gov.

(c) The Contractor shall comply with all provisions of Executive Order 13201 of February 17, 2001, and related implementing regulations at 29 CFR part 470, and orders of the Secretary of Labor.

(d) In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR part 470, which implements Executive Order 13201, or as are otherwise provided by law.

(e) The requirement to post the employee notice in paragraph (b) does not apply to--

(1) Contractors and subcontractors that employ fewer than 15 persons;

(2) Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive bargaining representative of the Contractor's employees;

(3) Contractor establishments or construction work sites located in a jurisdiction named in the definition of the United States in which the law of that jurisdiction forbids enforcement of union-security agreements;

(4) Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting requirements with respect to any of the Contractor's facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that--

(i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and

(ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or

(5) Work outside the United States that does not involve the recruitment or employment of workers within the United States.

(f) The Department of Labor publishes the official employee notice in two variations; one for contractors covered by the Railway Labor Act and a second for all other contractors. The Contractor shall--

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 20210, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

(2) Download a copy of the poster from the Office of Labor-Management Standards website at http://www.olms.dol.gov; or

(3) Reproduce and use exact duplicate copies of the Department of Labor's official poster.

(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c). For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States.

b. **Alternate V, Advance Payment Without Special Account** (May 2001), **Alternate II** (May 2001), and **Alternate IV** (April 1984), of FAR Clause **52.232-12, Advance Payments** (May 2001).

(a) *Requirements for payment.* Advance payments will be made under this contract (1) upon submission of properly certified invoices or vouchers by the contractor, and approval by the administering office, [*insert the name of the office designated under agency procedures*] , or (2) under a letter of credit. The amount of the invoice or voucher submitted plus all advance payments previously approved shall not exceed$[ ]. If a letter of credit is used, the Contractor shall withdraw cash only when needed for disbursements acceptable under this contract and report cash disbursements and balances as required by the administering office. The Contractor shall apply terms similar to this clause to any advance payments to subcontractors.

(b) *Use of funds*. The Contractor may use advance payment funds only to pay for properly allocable, allowable, and reasonable costs for direct materials, direct labor, and indirect costs. Determinations of whether costs are properly allocable, allowable, and reasonable shall be in accordance with generally accepted accounting principles, subject to any applicable subparts of Part 31 of the Federal Acquisition Regulation.

(c) *Repayment to the Government*. At any time, the Contractor may repay all or any part of the funds advanced by the Government. Whenever requested in writing to do so by the administering office, the Contractor shall repay to the Government any part of unliquidated advance payments considered by the administering office to exceed the Contractor's current requirements or the amount specified in paragraph (a) of this clause.

[(d) *Maximum payment*. When the sum of all unliquidated advance payments, unpaid interest charges, and other payments equal the total estimated cost of $ [ ] (not including fixed-fee, if any) for the work under this contract, the Government shall withhold further payments to the Contractor. Upon completion or termination of the contract, the Government shall deduct from the amount due to the Contractor all unliquidated advance payments and interest charges payable. The Contractor shall pay any deficiency to the Government upon demand. For purposes of this paragraph, the estimated cost shall be considered to be the stated estimated cost, less any subsequent reductions of the estimated cost, plus any increases in the estimated costs that do not, in the aggregate, exceed $ [ ] [*Insert an amount not higher than 10 percent of the stated estimated cost inserted in this paragraph*]. The estimated cost shall include, without limitation, any reimbursable cost (as estimated by the Contracting Officer) incident to a termination for the convenience of the Government. Any payments withheld under this paragraph shall be applied to reduce the unliquidated advance payments. If full liquidation has been made, payments under the contract shall resume.]

[(d) *Maximum payment.* When the sum of all unliquidated advance payments, unpaid interest charges, and other payments exceed [ ] percent of the contract price, the Government shall withhold further payments to the Contractor. On completion or termination of the contract, the Government shall deduct from the amount due to the Contractor all unliquidated advance payments and all interest charges payable. If previous payments to the Contractor exceed the amount due, the excess amount shall be paid to the Government on demand. For purposes of this paragraph, the contract price shall be considered to be the stated contract price of $[ ], less any subsequent price reductions under the contract, plus (1) any price increases resulting from any terms of this contract for price redetermination or escalation, and (2) any other price increases that do not, in the aggregate, exceed $ [*insert an amount not higher than 10 percent of the stated contract amount inserted in this paragraph*]. Any payments withheld under this paragraph shall be applied to reduce the unliquidated advance payments. If full liquidation has been made, payments under the contract shall resume.]

OR

[(e) *Interest*. No interest shall be charged to the prime Contractor for advance payments except for interest

charged during a period of default. The terms of this paragraph concerning interest charges for advance payments shall not apply to the prime Contractor.

(1) The Contractor shall pay interest to the Government on the daily unliquidated advance payments at the daily rate specified in subparagraph (e)(3) below. Interest shall be computed at the end of each calendar month for the actual number of days involved. For the purpose of computing the interest charge, the following shall be observed:

(i) Advance payments shall be considered as increasing the unliquidated balance as of the date of the advance payment check.

(ii) Repayments by Contractor check shall be considered as decreasing the unliquidated balance as of the date on which the check is received by the Government authority designated by the Contracting Officer.

(iii) Liquidations by deductions from payments to the Contractor shall be considered as decreasing the unliquidated balance as of the dates on which the Contractor presents to the Contracting Officer full and accurate data for the preparation of each voucher. Credits resulting from these deductions shall be made upon the approval of the reimbursement vouchers by the Disbursing Officer, based upon the Contracting Officer's certification of the applicable dates.

(2) Interest charges resulting from the monthly computation shall be deducted from any payments on account of the fixed-fee due to the Contractor. If the accrued interest exceeds the payment due, any excess interest shall be carried forward and deducted from subsequent payments of the contract price or fixed-fee. Interest carried forward shall not be compounded. Interest on advance payments shall cease to accrue upon (i) satisfactory completion or (ii) termination of the contract for the convenience of the Government. The Contractor shall charge interest on advance payments to subcontractors in the manner described above and credit the interest to the Government. Interest need not be charged on advance payments to nonprofit educational or research subcontractors for experimental, developmental, or research work.

(3) If interest is required under the contract, the Contracting Officer shall determine a daily interest rate based on the rate established by the Secretary of the Treasury under Pub. L. 92-41 (50 U.S.C. App., 1215(b)(2)). The Contracting Officer shall revise the daily interest rate during the contract period in keeping with any changes in the cited interest rate.

(4) If the full amount of interest charged under this paragraph has not been paid by deduction or otherwise upon completion or termination of this contract, the Contractor shall pay the remaining interest to the Government on demand.]

OR

[(e) *Interest*. No interest shall be charged to the prime Contractor for advance payments except for interest charged during a period of default. The terms of this paragraph concerning interest charges for advance payments shall not apply to the prime Contractor.

(1) The Contractor shall pay interest to the Government on the daily unliquidated advance payments at the daily rate in subparagraph (e)(3) of this clause. Interest shall be computed at the end of each calendar month for the actual number of days involved. For the purpose of computing the interest charge--

(i) Advance payments shall be considered as increasing the unliquidated balance as of the date of the advance payment check;

(ii) Repayments by Contractor check shall be considered as decreasing the unliquidated balance as of the date on which the check is received by the Government authority designated by the Contracting Officer; and

(iii) Liquidations by deductions from Government payments to the Contractor shall be considered as decreasing the unliquidated balance as of the date of the check for the reduced payment.

(2) Interest charges resulting from the monthly computation shall be deducted from payments, other than advance payments, due the Contractor. If the accrued interest exceeds the payment due, any excess interest shall be carried forward and deducted from subsequent payments. Interest carried forward shall not be compounded. Interest on advance payments shall cease to accrue upon satisfactory completion or termination of the contract for the convenience of the Government. The Contractor shall charge interest on advance payments to subcontractors in the manner described above and credit the interest to the Government. Interest need not be charged on advance payments to nonprofit educational or research subcontractors, for experimental, developmental, or research work.

(3) If interest is required under the contract, the Contracting Officer shall determine a daily interest rate based on the rate established by the Secretary of the Treasury under Pub. L. 92-41 (50 U.S.C. App., 1215(b)(2)). The Contracting Officer shall revise the daily interest rate during the contract period in keeping with any changes in the cited interest rate.

(4) If the full amount of interest charged under this paragraph has not been paid by deduction or otherwise upon completion or termination of this contract, the Contractor shall pay the remaining interest to the Government on demand.]

(f) *Lien on property under contract*. (1) All advance payments under this contract, together with interest charges, shall be secured, when made, by a lien in favor of the Government, paramount to all other liens, on the supplies or other things covered by this contract and on all material and other property acquired for or allocated to the performance of this contract, except to the extent that the Government by virtue of any other terms of this contract, or otherwise, shall have valid title to the supplies, materials, or other property as against other creditors of the Contractor.

(2) The Contractor shall identify, by marking or segregation, all property that is subject to a lien in favor of the Government by virtue of any terms of this contract in such a way as to indicate that it is subject to a lien and that it has been acquired for or allocated to performing this contract. If, for any reason, the supplies, materials, or other property are not identified by marking or segregation, the Government shall be considered to have a lien to the extent of the Government's interest under this contract on any mass of property with which the supplies, materials, or other property are commingled. The Contractor shall maintain adequate accounting control over the property on its books and records.

(3) If, at any time during the progress of the work on the contract, it becomes necessary to deliver to a third person any items or materials on which the Government has a lien, the Contractor shall notify the third person of the lien and shall obtain from the third person a receipt in duplicate acknowledging the existence of the lien. The Contractor shall provide a copy of each receipt to the Contracting Officer.

(4) If, under the termination clause, the Contracting Officer authorizes the contractor to sell or retain termination inventory, the approval shall constitute a release of the Government's lien to the extent that--

(i) The termination inventory is sold or retained; and

(ii) The sale proceeds or retention credits are applied to reduce any outstanding advance payments.

(g) *Insurance*. (1) The Contractor shall maintain with responsible insurance carriers--

(i) Insurance on plant and equipment against fire and other hazards, to the extent that similar properties are usually insured by others operating plants and properties of similar character in the same general locality;

(ii) Adequate insurance against liability on account of damage to persons or property; and

(iii) Adequate insurance under all applicable workers' compensation laws.

(2) Until work under this contract has been completed and all advance payments made under the contract have been liquidated, the Contractor shall--

(i) Maintain this insurance;

(ii) Maintain adequate insurance on any materials, parts, assemblies, subassemblies, supplies, equipment, and other property acquired for or allocable to this contract and subject to the Government lien under paragraph (f) of this clause; and

(iii) Furnish any evidence with respect to its insurance that the administering office may require.

(h) *Default*. (1) If any of the following events occur, the Government may, by written notice to the Contractor, withhold further payments on this contract:

(i) Termination of this contract for a fault of the Contractor.

(ii) A finding by the administering office that the Contractor has failed to--

(A) Observe any of the conditions of the advance payment terms;

(B) Comply with any material term of this contract;

(C) Make progress or maintain a financial condition adequate for performance of this contract;

(D) Limit inventory allocated to this contract to reasonable requirements; or

(E) Avoid delinquency in payment of taxes or of the costs of performing this contract in the ordinary course of business.

(iii) The appointment of a trustee, receiver, or liquidator for all or a substantial part of the Contractor's property, or the institution of proceedings by or against the Contractor for bankruptcy, reorganization, arrangement, or liquidation.

(iv) The commission of an act of bankruptcy.

(2) If any of the events described in subparagraph (h)(1) of this clause continue for 30 days after the written notice to the Contractor, the Government may take any of the following additional actions:

(i) Charge interest, in the manner prescribed in paragraph (e) of this clause, on outstanding advance payments during the period of any event described in subparagraph (h)(1) of this clause.

(ii) Demand immediate repayment by the Contractor of the unliquidated balance of advance payments.

(iii) Take possession of and, with or without advertisement, sell at public or private sale all or any part of the property on which the Government has a lien under this contract and, after deducting any expenses incident to the sale, apply the net proceeds of the sale to reduce the unliquidated balance of advance payments or other Government claims against the Contractor.

(3) The Government may take any of the actions described in subparagraphs (h)(1) and (h)(2) of this clause it considers appropriate at its discretion and without limiting any other rights of the Government.

(i) *Prohibition against assignment*. Notwithstanding any other terms of this contract, the Contractor shall not assign this contract, any interest therein, or any claim under the contract to any party.

(j) *Information and access to records*. The Contractor shall furnish to the administering office (1) monthly or at other intervals as required, signed or certified balance sheets and profit and loss statements, and, (2) if requested, other information concerning the operation of the contractor's business. The Contractor shall provide the authorized Government representatives proper facilities for inspection of the Contractor's books, records, and accounts.

(k) *Other security*. The terms of this contract are considered to provide adequate security to the Government for advance payments; however, if the administering office considers the security inadequate, the Contractor shall furnish additional security satisfactory to the administering office, to the extent that the security is available.

(l) *Representations*. The Contractor represents the following:

(1) The balance sheet, the profit and loss statement, and any other supporting financial statements furnished to the administering office fairly reflect the financial condition of the Contractor at the date shown or the period covered, and there has been no subsequent materially adverse change in the financial condition of the Contractor.

(2) No litigation or proceedings are presently pending or threatened against the Contractor, except as shown in the financial statements.

(3) The Contractor has disclosed all contingent liabilities, except for liability resulting from the renegotiation of defense production contracts, in the financial statements furnished to the administering office.

(4) None of the terms in this clause conflict with the authority under which the Contractor is doing business or with the provision of any existing indenture or agreement of the Contractor.

(5) The Contractor has the power to enter into this contract and accept advance payments, and has taken all necessary action to authorize the acceptance under the terms of this contract.

(6) The assets of the Contractor are not subject to any lien or encumbrance of any character except for current taxes not delinquent, and except as shown in the financial statements furnished by the Contractor. There is no current assignment of claims under any contract affected by these advance payment provisions.

(7) All information furnished by the Contractor to the administering office in connection with each request for advance payments is true and correct.

(8) These representations shall be continuing and shall be considered to have been repeated by the submission of each invoice for advance payments.

(m) *Covenants*. To the extent the Government considers it necessary while any advance payments made under this contract remain outstanding, the Contractor, without the prior written consent of the administering office, shall not--

(1) Mortgage, pledge, or otherwise encumber or allow to be encumbered, any of the assets of the Contractor now owned or subsequently acquired, or permit any preexisting mortgages, liens, or other encumbrances to remain on or attach to any assets of the Contractor which are allocated to performing this contract and with respect to which the Government has a lien under this contract;

(2) Sell, assign, transfer, or otherwise dispose of accounts receivable, notes, or claims for money due or to become due;

(3) Declare or pay any dividends, except dividends payable in stock of the corporation, or make any other distribution on account of any shares of its capital stock, or purchase, redeem, or otherwise acquire for value any of its stock, except as required by sinking fund or redemption arrangements reported to the administering office incident to the establishment of these advance payment provisions;

(4) Sell, convey, or lease all or a substantial part of its assets;

(5) Acquire for value the stock or other securities of any corporation, municipality, or Governmental authority, except direct obligations of the United States;

(6) Make any advance or loan or incur any liability as guarantor, surety, or accommodation endorser for any party;

(7) Permit a writ of attachment or any similar process to be issued against its property without getting a release or bonding the property within 30 days after the entry of the writ of attachment or other process;

(8) Pay any remuneration in any form to its directors, officers, or key employees higher than rates provided in existing agreements of which notice has been given to the administering office, accrue excess remuneration without first obtaining an agreement subordinating it to all claims of the Government, or employ any person at a rate of compensation over $[ ] a year;

(9) Change substantially the management, ownership, or control of the corporation;

(10) Merge or consolidate with any other firm or corporation, change the type of business, or engage in any transaction outside the ordinary course of the Contractor's business as presently conducted;

(11) Deposit any of its funds except in a bank or trust company insured by the Federal Deposit Insurance Corporation or a credit union insured by the National Credit Union Administration;

(12) Create or incur indebtedness for advances, other than advances to be made under the terms of this contract, or for borrowings;

(13) Make or covenant for capital expenditures exceeding $ in total;

(14) Permit its net current assets, computed in accordance with generally accepted accounting principles, to become less than $[ ] ; or

(15) Make any payments on account of the obligations listed below, except in the manner and to the extent provided in this contract:

[*List the pertinent obligations*]

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS:

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal	See Attachment Section at the end of this RFP
Attachment 2:	Proposal Intent Response Sheet	See Attachment Section at the end of this RFP
Attachment 3:	Statement of Work	See Attachment Section at the end of this RFP
Attachment 4:	Information Technology Systems Security - Prospective Offeror Non-Disclosure Agreement	http://rcb.cancer.gov/rcb-internet/forms/IT-security-nondisclosure.pdf

TECHNICAL PROPOSAL ATTACHMENTS: (The following attachments must be completed, where applicable, and submitted with the Technical Proposal.)

Attachment No.	Title	Location
Attachment 5:	Targeted/Planned Enrollment Table	http://rcb.cancer.gov/rcb-internet/forms/enroll-table.pdf
Attachment 6:	Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Attachment 7:	Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Attachment 8:	Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms/form7.pdf
Attachment 9:	Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (formerly Optional Form 310	http://rcb.cancer.gov/rcb-internet/forms/of310.pdf
Attachment 10:	Project Objectives, NIH 1688-1	http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf

BUSINESS PROPOSAL ATTACHMENTS: (The following attachments must be completed, where applicable, and submitted with the Business Proposal.)

Attachment No.	Title	Location
Attachment 11:	Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Attachment 12:	Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet	http://www.niaid.nih.gov/contract/forms.htm http://ocm.od.nih.gov/contracts/spsh/spshexcl.xls
Attachment 13:	Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Attachment 14:	Certificate of Current Cost or Pricing Data	http://rcb.cancer.gov/rcb-internet/forms/cert-current-cost.pdf
Attachment 15:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://www.niaid.nih.gov/contract/forms/sf-lll.pdf

INFORMATIONAL ATTACHMENTS: (The following Attachments and Reports will become part of any contract resulting from this RFP and will be required during contract performance.)

Attachment No.	Title	Location
Attachment 16:	Invoice/Financing Request Instructions--Cost-Reimbursement, NIH(RC)-1	http://rcb.cancer.gov/rcb-internet/forms/rc1.pdf
Attachment 17:	Invoice Instructions for NIH Fixed-Price Contracts, NIH(RC)-2	http://rcb.cancer.gov/rcb-internet/forms/rc2.pdf
Attachment 18:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Attachment 19:	Financial Report of Individual Project/Contract, NIH 2706	http://www.niaid.nih.gov/contract/forms/nih-2706.pdf
Attachment 20:	Instructions for Completing Form NIH 2706	http://www.niaid.nih.gov/contract/forms/instructions2706.pdf
Attachment 21:	Privacy Act System of Records *System of Records No. _____ is applicable to this RFP.*	http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm
Attachment 22:	Safety and Health, HHSAR Clause 352.223-70	http://www.niaid.nih.gov/contract/forms/form10.pdf
Attachment 23:	Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Attachment 24:	Research Patient Care Costs, NIH(RC)-11	http://www.niaid.nih.gov/contract/forms/nih-rc-11.pdf

Attachment 25:	Inclusion Enrollment Report	http://rcb.cancer.gov/rcb-internet/forms/inclusion-enrollment.pdf
Attachment 26:	Government Property Schedule	See Attachment Section
Attachment 27:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://www.niaid.nih.gov/contract/forms/sf-lll.pdf
Attachment 28:	Commitment To Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

SECTION K can be accessed electronically from the INTERNET at the following address:

http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE SECTION K AND SUBMIT IT AS PART OF YOUR BUSINESS PROPOSAL.

SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Provision 52.215-1 (January 2004)]

(a) *Definitions*. As used in this provision--

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"In writing", *"writing"*, or *"written"* means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time,*" if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals*. (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

(i) The solicitation number;

(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);

(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an

agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals*. (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(*1*) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(*2*) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(*3*) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date*. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

(e) *Restriction on disclosure and use of data.* (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
>
> The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.
>
> If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
>
> The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

> "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(f) *Contract award*. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.

(ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.

(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;

(iv) A summary of the rationale for award.

(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

b. "**JUST IN TIME**"

This RFP contains special procedures for the submission of business management proposals. These special procedures are designed to reduce the administrative burden on offerors without compromising the information during the initial evaluation of proposals. Certain documents will not longer be required to be submitted with initial proposals, but will be requested at a later stage in the competitive process. Specifically, the travel policy, the annual financial statement, the total compensation plan, the subcontracting plan, and certain types of cost/pricing information will only be required to be submitted from those offerors included in the competitive range, or the apparent successful offeror. The special procedures for submission of this documentation are set forth in detail below:

Travel Policy. The offeror's (and any proposed subcontractor's) written travel policy shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a travel policy as a part of their final proposal revision.

Annual Report. The offeror's most recent annual report shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a copy of their most recent annual report as a part of their final proposal revision.

Total Compensation Plan. The offeror's total compensation plan shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a total compensation plan as a

part of their final proposal revision.

Subcontracting Plan. The offeror's Small Business Subcontracting Plan shall **not** be submitted with the initial business proposal. Only those offerors included in the competitive range will be required to submit **an acceptable** subcontracting plan.

Cost/Pricing Information. The offeror's business proposal shall include the basic cost/pricing information specified in Section L.2.c.(1) of this RFP. In addition, the Government may require offerors included in the competitive range to submit additional information substantiating their proposed costs or prices. This additional cost/pricing information will be requested after establishment of the competitive range, and potentially includes payroll documentation, vendor quotes, invoice prices, and/or any other information deemed necessary by the contracting officer to evaluate the reasonableness of the price or to determine cost realism. The information may also include submission and certification of cost or pricing data.

c. **NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541710 .

(2) The small business size standard is 500 .

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in EVERY solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

d. **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that up to four (4) Awards will be made from this solicitation and that the awards will be made on/about August 1, 2006.

It is anticipated that the awards from this solicitation will be multiple-year cost reimbursement type completion contracts with a period of performance of eight years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

e. **ESTIMATE OF EFFORT**

It is expected that completion type contracts will be awarded as a result of this RFP. The level of effort devoted to this project must be compatible with the scientific and technical approach proposed to cover the activities in the Statement of Work. Professional, technical, and support staff should have experience pertinent to that required for a Field Center approved in the Statement of Work. The following staffing patterns are to be considered broad guidelines and are not inclusive of all staffing positions, only the Principal and Co-Principal Investigators. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

Principal Investigator	25% (each field center for all years)

Co-Principal Investigator	10% (each field center for all years)
Other Investigators	10% (each field center for all years)

f, **REFERENCE MATERIAL**

RFP NHLBI-HC-06-01 HISPANIC COMMUNITY HEALTH STUDY - COORDINATING CENTER

g. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

h. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

i. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

j. **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors are specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

k. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

l. **SERVICE OF PROTEST** (AUGUST 1996) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer
Contract Operations Branch
National Heart, Lung, and Blood Instiute, NIH
6701 Rockledge Drive, MSC 7902
Bethesda, Maryland MD 20892-7902

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

m. **LATE PROPOSALS AND REVISIONS**, HHSAR 352.215-70

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

n. **UNIFORM RESOURCE LOCATORS (URLs) IN CONTRACT PROPOSALS**

All proposals must be self-contained within the specific page limitations cited elsewhere in this solicitation. Unless otherwise specified, URLs/Internet addresses shall not be used to provide information necessary to the review because reviewers are under no obligation to review the Internet sites.

o. **PAGE AND FORMATTING LIMITATIONS**

The Technical Plan (objectives, approach, methods and procedures, and schedule) of the Technical Proposal shall not exceed 50 single-sided pages or 25 double-sided pages. This page limitation does not apply to the cover sheet, abstract, table of contents, personnel, facilities, equipment and resources, other considerations, other support, cost information, and literature cited. Appendices shall be limited to 100 single-sided pages or 50 double-sided pages. Pages in excess of this will be deleted and will be neither read nor evaluated. Each page of the Technical Proposal must be numbered sequentially. Offerors are encouraged to limit the overall size of the Technical Proposal, inclusive of appendices, attachments, etc. Note that although no page limit has been placed on the Business Proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

Type density and size must be 10 to 12 points. If constant spacing is used, 15 cpi (characters per inch) or fewer shall be used, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around.

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) **Contract Type and General Clauses**

It is contemplated that a cost-reimbursement completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addresses, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(3) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD.)

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS). However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in Part IV, Section M of this RFP.

(7) **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(8) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurement, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(9) **Standards for Privacy of Individually Identifiable Health Information**

The Department of Health and Human Services (DHHS) issued final modifications to the "Standards for Privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities" must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply.

Decisions about the applicability and implementation of the Privacy Rule reside with the contractor and his/her institution. The OCR Web site (http://www.hhs.gov/ocr/) provides information of the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, award, and administration of grants, cooperative agreements and contracts can be found at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

(10) **Obtaining and Disseminating Biomedical Research Resources**

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they

impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: http://ott.od.nih.gov/NewPages/64FR72090.pdf.

(a) **Sharing Research Data**

*Note: The NIH Guide announcement referenced below states that this policy is applicable to "all investigator-initiated applications with direct costs greater than $500,000 in any single year." This is an overall grant policy which requires that an applicant must seek agreement by NIH to accept assignment of their application in advance of the submission date. As such, this policy has no correlation to the contract process, therefore, the threshold is not applicable to contracts. Thus, this article applies to **any** contract that may generate research data.*

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

If the resultant contract is part of a collaborative program involving multiple sites, the data sharing will be governed by a dissemination plan to be developed jointly following award. Offerors must include in their proposals a statement of willingness to work collaboratively after award with the other funded sites to prepare a joint dissemination plan. Coordinating Center proposals should describe methods to coordinate the dissemination planning and implementation. The Coordinating Center must include a budget and justification for any additional costs of this collaborative effort.

(11) **Privacy Act - Treatment of Proposal Information**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(12) **Selection of Offerors**

a) The acceptability of the scientific and technical portion of each contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract-

(1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or

otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

(2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is NHLBI's policy to conduct discussions with all offerors in the competitive range, NHLBI reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The NHLBI reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NHLBI requirements. Synopses of awards exceeding $25,000 will be published in FedBizOpps.

(13) **Small Business Subcontracting Plan**

This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.a. of this RFP.

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the apparent successful offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, Attachment to this RFP is an example of such a plan.

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

(6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone,

Veteran-Owned, and/or Service Disabled Veteran-Owned Small Business Concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this RFP are as follows:

___% for Small Business; ___% for Small Disadvantaged Business; ___% for Women-Owned Small Business; ___% for HUBZone Small Business; and ___% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

(14) **HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

(15) **Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled “Extent of Small Disadvantaged Business Participation” as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes.

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) code, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). TheNAICS codes can be found at:

http://www.sba.gov/size

The Department of Commerce website for the annual determination for NAICS codes* is:

http://www.arnet.gov/References/sdbadjustments.htm.

**Note: Public Law 103-355 which authorized the SDB Price Evaluation Adjustment (PEA) and associated percentages/factors expired on December 9, 2004, therefore, the percentages shown at this website are no longer applicable.*

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Subsector(s). The applicable authorized NAICS Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation.

An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Subsector 223

	SDB Percentage of Total Contract Value	**SDB Dollars**
Total Contract Value- $1,000,000	25%	$250,000
SDB Participation by Prime	10%	$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	$150,000

*Note: FAR Subpart 9.6 defines “Contractor team arrangements” to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

(16) **Salary Rate Limitation in Fiscal Year 2005**

Offerors are advised that pursuant to P.L. 108-447, no NIH Fiscal Year 2005 (October 1, 2004 - September 30, 2005) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. 108-447 applies only to Fiscal Year 2005 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 108-447 states in pertinent part:

"None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level I*."

LINK TO EXECUTIVE SCHEDULE SALARIES: http://www.opm.gov/oca/05tables/html/ex.asp

***Note to Offerors:** The current Fiscal Year Executive Level I Salary Rate should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award will be required to be in compliance with the current Fiscal Year 2005 Executive Level I Salary rates.*

(17) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4) the Institution will otherwise comply with the regulations.

Institutional Management of Conflicting Interests

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(i) public disclosure of significant financial interests;

(ii) monitoring of research by independent reviewers;

(iii) modification of the research plan;

(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;

(v) divestiture of significant financial interests; or

(vi) severance of relationships that create actual or potential conflicts of interests.

(b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(18) **ROTC Access and Federal Military Recruiting on Campus**

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

(19) **Electronic and Information Technology Accessibility**

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR part 1194) require that all EIT acquired must ensure that:

a. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and

b. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

This requirement includes the development, maintenance, and/or use of EIT products/services, therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards.

Further information about Section 508 is available via the Internet at http://www.section508.gov .

(20) **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003).

b) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

c) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

b. TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) Technical Discussion

The technical discussion included in the technical proposal should respond to the items set forth below:

a) Project Objectives, NIH-1688-1

The offeror shall insert a completed NIH Form 1688-1, Project Objective, as provided in Section J, Attachments, behind the Title Page of each copy of the proposal, along with the "Government Notice for Handling Proposals." The NIH Form 1688-1 is to be completed as follows:

- For an **Institution of Higher Education:** The form MUST be completed in its entirety.
- For **OTHER** than an Institution of Higher Education: The starred items (Department, Service, Laboratory or Equivalent, and Major Subdivision) should be left blank.

The information required under the "Summary of Objectives" portion of the form MUST meet the requirements set forth in the section of the form entitled, **"INSTRUCTIONS:"**

b) Statement of Work

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

c) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

-The specific items or expertise they will provide.

-Their availability to the project and the amount of time anticipated.

-Willingness to act as a consultant.

-How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (Section M., hereof).

(3) **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

IMPORTANT NOTE TO OFFERORS: The following 12 paragraphs (5) through (16) shall be addressed in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

(5) **Human Subjects**

The following notice is applicable when contract performance is expected to involve risk to human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (MARCH 2005)

(a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protections (OHRP), Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

(b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR Part 46.

(c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

(d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The OpDiv will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consultation with OHRP, (telephone: 301-496-7005), is recommended.

(e) In accordance with 45 CFR Part 46, prospective Contractors being considered for award shall be required to file with OHRP an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. The contracting officer will direct the offeror/contractor to the OHRP IRB Registration and Assurance Filing website, found at http://www.hhs.gov/ohrp/ or to the physical address if the offeror/contractor cannot access the Internet. HHS regulations for the protection of human subjects may be found at:

http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr46_01.html

(f) It is recommended that OHRP be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(End of provision)

(6) **Instructions to Offerors Regarding Protection of Human Subjects**

Offerors must address the following human subjects protections issues if this contract will be for research involving human subjects (note: under each of the following points below, the offeror should indicate whether the information provided relates to the primary research site, or to a collaborating performance site(s), or to all sites:

(a) Risks to the subjects

Human Subjects Involvement and Characteristics:

- Describe the proposed involvement of human subjects in response to the solicitation.

- Describe the characteristics of the subject population, including their anticipated number, age range, and health status.

- Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.

Sources of Materials:

- Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Potential Risks:

- Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.

- Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

(b) Adequacy of Protection Against Risks

Recruitment and Informed Consent:

- Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document for the contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.

Protection Against Risk:

- Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.

- Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.

- In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

(c) Potential Benefits of the Proposed Research to the Subjects and Others

- Discuss the potential benefits of the research to the subjects and others.

- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

(d) Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.

- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

Note: If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of offeror's certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether the FDA has withheld or restricted use of the test article.

Collaborating Site(s)

When research involving human subjects will take place at collaborating site(s) or other performance site(s), the offeror must provide in this section of its proposal a list of the collaborating sites and their assurance numbers. Further, if you are awarded a contract, you must obtain in writing, and keep on file, an assurance from each site that the previous points have been adequately addressed at a level of attention that is at least as high as that documented at your organization. Site(s) added after an award is made must also adhere to the above requirements.

(7) **Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at http://ohsr.od.nih.gov/cbt/. You may download the information at this site at no cost and modify it, if desired. The University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at

http://www.centerwatch.com/order/pubs_profs_protect.html.

In addition, the NCI sponsors an online training course at:

http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp.

If an institution already has developed educational programs on the protection of research participants, completion of these programs also will satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the contracting officer with the title of the education program and a one sentence description of the program that the replacement has completed.

(8) **Inclusion of Women and Minorities in Research Involving Human Subjects**

It is NIH policy that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an Institute/Center Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43), ***and applies to research subjects of all ages***.

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended October 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

These guidelines contain a definition of **clinical research** adopted in June 2001, as: "(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research," at:

(http://www.nih.gov/news/crp/97report/execsum.htm).

Information Required for ALL Clinical Research Proposals

This solicitation contains a review criterion addressing the adequacy of: (1) the offeror's plans for inclusion of women and minorities in the research proposed; or (2) the offeror's justification(s) for exclusion of one or both groups from the research proposed.

Provide information on the composition of the proposed study population in terms of sex/gender and racial/ethnic groups and provide a rationale for selection of such subjects in response to the requirements of the solicitation. The description may include (but is not limited to) information on the population characteristics of the disease or condition being studied in the planned research, and/or

described in the statement of work, national and local demography, knowledge of the racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned research.

The proposal must include the following information:

- A description of the subject selection criteria
- The proposed dates of enrollment (beginning and end)
- A description of the proposed outreach programs for recruiting women and minorities as subjects
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group
- The proposed sample composition using the "Targeted/Planned Enrollment Table"(see Section J, Attachments)

NOTE 1: *For all proposals, use the ethnic and racial categories and complete the "Targeted/Planned Enrollment Table in accordance with the Office of Management and Budget (OMB) Directive No. 15, which may be found at: http://www.whitehouse.gov/OMB/fedreg/ombdir15.html.*

NOTE 2: *If this is an Indefinite Delivery, Indefinite Quantity (IDIQ) or Requirements contract as defined in FAR 16.5, the proposal should describe in general terms how it will comply with each bulleted item above for each task order. When the Government issues a task order request for proposal, each of the bulleted information items must be fully and specifically addressed in the proposal.*

Standards for Collecting Data. When you, as a contractor, are planning data collection items on race and ethnicity, you shall use, at a minimum, the categories identified in OMB Directive No. 15. The collection of greater detail is encouraged. However, you should design any additional, more detailed items so that they can be aggregated into these required categories. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on race and ethnicity. When you collect race and ethnicity separately, you must collect ethnicity first. You shall offer respondents the option of selecting one or more racial designations. When you collect data on race and ethnicity separately, you shall also make provisions to report the number of respondents in each racial category who are Hispanic or Latino. When you present aggregate data, you shall provide the number of respondents who selected only one category, for each of the five racial categories. If you collapse data on multiple responses, you shall make available, at a minimum, the total number of respondents reporting "more than one race." Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

In addition to the above requirements, solicitations for **NIH defined Phase III clinical trials**[1] require that*:* a) all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm,

Definitions - Significant Difference), by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity differences.

[1] See NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, for the Definition of an "NIH-Defined Phase III clinical trial.

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Also, the proposal must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups, OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Use the form entitled, "Targeted/Planned Enrollment Table," when preparing your response to the solicitation requirements for inclusion of women and minorities. (See Section J-List of Documents, Exhibits and Other Attachments of the RFP)

Unless otherwise specified in this solicitation, the Government has determined that the work required by this solicitation does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)

Use the form entitled, "Inclusion Enrollment Report," for reporting in the resultant contract.

(9) **Inclusion of Children in Research Involving Human Subjects**

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are *clear and compelling* reasons not to include them. (See examples of Justifications for Exclusion of Children below). For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 21 years.

All offerors proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:

http://www.nih.gov/grants/guide/notice-files/not98-024.html

Offerors also may obtain copies from the contact person listed in the RFP.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. The "Human Subjects" section of your technical proposal should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. This solicitation contains a review criterion addressing the adequacy of: (1) the plans for including children as appropriate for the scientific goals of the research; and/or (2) the justification of exclusion of children or exclusion of a specific age range of children.

When children are included, the plan also must include a description of: (1) the expertise of the investigative team for dealing with children at the ages included; (2) the appropriateness of the available facilities to accommodate the children; and, (3) the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation.

Justifications for Exclusion of Children

It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

- The objective of the solicitation is not relevant to children.

- There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.

- The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.

- A separate, age-specific study in children is warranted and preferable. Examples include:
- The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or
- The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
- Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages of different age-related metabolic processes); or
- Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or

- Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children);
- Other special cases justified by the offeror and found acceptable to the review group and the Institute Director

Definition of a Child

For the purpose of this solicitation, a child is defined as an individual under the age of 21 years.

The definition of child described above will pertain to this solicitation (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

(10) **Data and Safety Monitoring in Clinical Trials and Observational Studies**

For informational purposes, the contractor is directed to the full text of the NHLBI policies regarding Oberservational Study Monitoring Boards, which may be found at the following web sites:

Establishing Data and Safety Monitoring Boards and Observational Study Monitoring Boards (http://www.nhlbi.nih.gov/funding/policies/dsmb_est.htm)

Guidelines for Data Quality Assurance in Clinical Trials and Observational Studies (http://www.nhlbi.nih.gov/funding/policies/dataqual.htm)

Responsibilities of OSMBs Appointed by the NHLBI (http://www.nhlbi.nih.gov/funding/policies/osmb_inst.htm)

(11) **Research Involving Human Fetal Tissue**

Human Fetal Tissue means tissue or cells obtained from a dead human fetus, including human embryonic stem cells, human pluripotent stem cells and human embryonic germ cells.

The governing federal statute is the Public Health Service Act, 42 U.S.C. 289g-1 and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and http://grants1.nih.gov/grants/guide/notice-files/not93-235.html and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

By signing the face page of the proposal, the offeror (authorized institutional official) certifies that researchers using human fetal tissue are in compliance with 42 USC 289g-2. This statute specifically prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for valuable consideration. "Valuable consideration" is a concept similar to profit, and does not include reasonable payment for costs associated with the collection processing, preservation, storage, quality control or transportation of these tissues.

Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local law.

(12) **Research Involving Prisoners as Subjects**

a. HHS Regulations at 45 CFR Part 46, Subpart C provide additional protections pertaining to biomedical and behavioral research involving prisoners or those individuals who, during the period of the contract become prisoners, as subjects. These regulations also set forth the duties of the Institutional Review Board (IRB) where prisoners are involved in the research. HHS-funded research involving prisoners as subjects may not proceed until the Office for Human Research Protections (OHRP) issues approval, in writing, as required by 45 CFR 46.306(a)(2). In addition, OHRP Guidance on the Involvement of Prisoners in Research may be found at:

http://ohrp.osophs.dhhs.gov/humansubjects/guidance/prisoner.htm

b. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

On June 20, 2003 the Secretary of HHS waived the applicability of certain provisions of Subpart C of 45 CFR Part 46, (Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects) to specific types of epidemiological research involving prisoners as subjects.

The applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain epidemiological research conducted or funded by DHHS is waived when:

1. The sole purposes are:

a) to describe the prevalence or incidence of a disease by identifying all cases, or

b) to study potential risk factor associations for a disease, and

2. The Institution responsible for the conduct of the research certifies to the OHRP that the Institutional Review Board (IRB) approved the research and fulfilled its duties under 45 CFR 46.305(a)(2-7) and determined and documented that:

a) the research presents no more than minimal risk, and

b) no more than inconvenience to the prisoner-subjects, and

c) prisoners are not a particular focus of the research.

For more information about this Waiver see http://www.hhs.gov/ohrp/special/prisoners/Prisoner waiver 6-20-03.pdf

(13) **Research Involving Recombinant DNA Molecules (including Human Gene Transfer Research)**

Recombinant DNA Molecules are either 1) molecules that are constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or 2) DNA molecules that result from the replication of those described in 1).

The NIH Guidelines for Research Involving Recombinant DNA Molecules (http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html and the May 28, 2002 Notice, Compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules, at:

(http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html)

and any subsequent revisions to the Guide Notice) stipulates biosafety and containment measures for recombinant DNA research and delineates critical, ethical principles and key safety reporting requirements for human gene transfer research (See Appendix M of the NIH Guidelines). These guidelines apply to both basic and clinical research studies.

The Recombinant DNA Advisory Committee (RAC) is charged with the safety of manipulation of genetic material through the use of recombinant DNA techniques. Prior to beginning any clinical trials involving the transfer of recombinant DNA to humans, the trial must be registered with the RAC. If this contract involves new protocols that contain unique and//or novel issues, the RAC must discuss them in a public forum and then the Institutional Biosafety Committee (IBC), the Institutional Review Board (IRB), and the project officer and contracting officer must approve the protocol prior to the start of the research.

Failure to comply with these requirements may result in suspension, limitation, or termination of NIH funding for any work related to Recombinant DNA Research or a requirement for the contracting officer's prior approval of any or all Recombinant DNA projects under any contract awarded from this solicitation. This includes the requirements of the Standing Institutional Biosafety Committee (IBC) (See http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm).

As specified in Appendix M-1-C-4 of the NIH Guidelines, any serious adverse event must be reported immediately to the IRB, the IBC, the Office for Human Research Protections (if applicable), and the NIH Office for Biotechnology Activities (OBA), followed by the filing of a written report with each office/group and copies to the project officer and contracting officer.

(http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_M.htm#_Toc7255836)

(14) **Human Embryonic Germ Cell (HEGC) Research**

1. Guidelines.

Research use of human embryonic germ cells derived from fetal tissue with Federal funds requires review of compliance with the NIH Guidelines for Research Using Human Pluripotent Stem Cells (http://stemcells.nih.gov/policy/guidelines.asp) (only the information regarding human embryonic germ cells is relevant). Embryonic germ cells are pluripotent stem cells derived from human embryos. See NIH Guide for Grants and Contracts Notice NOT-OD-02-049, requiring that offerors/contractors submit certain documents to the Human Pluripotent Stem Cell Review Group (HPSCRG), which will be reviewed in a public meeting. Research using human embryonic germ cells may not be performed prior to approval by the HPSCRG.

All offerors should read the "NIH Guidelines" (http://stemcells.nih.gov/policy/guidelines.asp) if they either: (1) propose to respond to the Statement of Work requirements by conducting research that uses human embryonic germ cells or, (2) are responding to a Statement of Work that requires the use of human embryonic germ cells.

Offerors may obtain copies of these Guidelines from the website above or from the contact person listed in this solicitation.

2. Procedure for Required Review by Human Pluripotent Stem Cell Review Group (HPSCRG)

If the offeror intends to fulfill the requirements of the Statement of Work by performing research using human embryonic germ cells, it must so state in its proposal.

If the offeror's proposal includes research using human embryonic germ cells and it receives a contract award, the contractor may not perform any research using these human embryonic germ cells until the Human Pluripotent Stem Cell Review Group (HPSCRG) has reviewed and approved the documentation furnished as prescribed in "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells" (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html) and the contracting officer has notified the contractor of the approval in writing.

The resultant contract will be divided into discrete phases or option period(s). During Option Period(s)/Phase(s) of the contract, the contractor shall submit the original and two copies of the required documentation and assurances that address the areas covered in "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells," at:

(http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html)

to the contracting officer. This documentation will be forwarded for review and approval to the HPSCRG.

If the HPSCRG disapproves the documentation presented by the contractor, the Contracting Officer may elect to either terminate the contract in accordance with the Termination for Convenience clause of the contract OR determine not to exercise subsequent option(s) as appropriate based the terms of the specific contract. Otherwise, when the HPSCRG approves the documentation, the contracting officer will notify the contractor in writing that research using the human embryonic germ cells may commence.

Research involving the use of human embryonic germ cells shall not be conducted under the contract until the HPSCRG review and approval have been obtained, and the contracting officer has provided written notice of such approval to the contractor.

(15) **Human Embryonic Stem Cell (HESC) Research**

On August 9, 2001, the President announced the criteria that must be met for Federal funds to be used for research on existing human embryonic stem cell lines. These criteria were subsequently published by the NIH at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. The following eligibility criteria must be met:

1. The derivation process (which commences with the removal of the inner cell mass from the blastocyst) must have already been initiated prior to August 9, 2001;
2. Prior to August 9, 2001, the embryo from which the stem cell line was derived no longer had the possibility of development as a human being;
3. The stem cells must have been derived from an embryo that was created for reproductive purposes;
4. The embryo was no longer needed for these purposes;
5. Informed consent must have been obtained for the donation of the embryo;

6. No financial inducements were provided for the donation of the embryo.

To facilitate research using human embryonic stem cells, the NIH has established a Human Embryonic Stem Cell Registry ("the NIH Registry") that lists the human embryonic stem cells that meet the eligibility criteria. This registry is available at: http://stemcells.nih.gov/registry/.

Research involving the derivation of new stem cells from human embryos or the use of human embryonic stem cells that are not listed on the NIH Human Embryonic Stem Cell Registry may not be conducted with Federal funding.

If a particular human embryonic stem cell line has not been required by the Statement of Work, an offeror proposing research involving human embryonic stem cells must cite a human embryonic stem cell line that is listed in the NIH Registry in its proposal.

c. BUSINESS PROPOSAL INSTRUCTIONS

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) Cost and Pricing Data

Note: This data is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this data are outlined in SECTION L.1.b. of this RFP.

1. General Instructions

A. You must provide the following information on the first page of your pricing proposal:

(1) Solicitation, contract, and/or modification number;

(2) Name and address of offeror;

(3) Name and telephone number of point of contact;

(4) Name of contract administration office (if available);

(5) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);

(6) Proposed cost; profit or fee; and total;

(7) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;

(8) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;

(9) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;

(10) Date of submission; and

(11) Name, title and signature of authorized representative.

B. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

C. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including--

(1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and

(2) The nature and amount of any contingencies included in the proposed price.

D. You must show the relationship between contract line item prices and the total contract price. You must attach cost-element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.

E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.

F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.

G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.

H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

2. **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

A. **Materials and services**. Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed

by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.

(1) *Adequate Price Competition*. Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205-26(e)).

(2) *All Other*. Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either $10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

B. **Direct Labor**. Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.

C. **Indirect Costs**. Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.

D. **Other Costs**. List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

E. **Royalties**. If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:

(1) Name and address of licensor.

(2) Date of license agreement.

(3) Patent numbers.

(4) Patent application serial numbers, or other basis on which the royalty is payable.

(5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).

(6) Percentage or dollar rate of royalty per unit.

(7) Unit price of contract item.

(8) Number of units.

(9) Total dollar amount of royalties.

(10) If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).

F. **Facilities Capital Cost of Money**. When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

3. **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (Section J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

4. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

5. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books,

records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

NOTE: Data substantiating the costs or prices proposed (i.e. payroll documentation, vendor quotes, invoice price, etc.) shall not be submitted with the initial proposal. This information will be requested from the offeror during the negotiation process. The initial proposal need only indicate from what source the proposed costs and prices are substantiated.

(3) **Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data** [FAR Clause 52.215-20 (October 1997)]

(a) Exceptions from cost or pricing data.

(1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

Alternate I (October 1997). As prescribed in 15.408(l), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

(b)(1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

The format specified in paragraph L.2.c.(4) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

(4) **Qualifications of the Offeror**

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror

or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

Performance history is defined as meeting contract objectives within delivery and cost schedules on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(5) **Other Administrative Data**

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractor's Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

c) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38**, (May 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).

(2) The offeror's name and remittance address, as stated in the offer.

(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.

(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.

(5) The offeror's account number and the type of account (checking, savings, or lockbox).

(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.

(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

d) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

e) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

f) **Facilities Capital Cost of Money**, FAR 52.215-16, (June 2003)

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ] The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an

allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(6) **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.

c) The amount of time and facilities available to this project.

d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.

f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm

(7) **Proposer's Annual Financial Report**

[NOTE: This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.a. of this RFP.]

All offerors included in the competitive range will be required to submit a copy of the organization's most recent annual financial report.

(8) **Representations and Certifications**

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(9) **Travel Costs/Travel Policy**

a) **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

[NOTE: This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.a. of this RFP.]

All offerors included within the competitive range will be required to submit one copy of their written travel policy. A written travel policy for any proposed subcontractors shall also be submitted at that time. If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

10. **NOTES TO OFFERORS FROM THE HISPANIC COMMUNITY HEALTH STUDY STATEMENT OF WORK FOR BUSINESS AND TECHNICAL PROPOSAL PREPARATION**

In the Statement of Work, per part C. Detailed Description of the Technical Requirements, item No. 3:

[Note 1 to Offeror: Separate justification, plans and budgets should be developed for two options for a facility, one a facility located in the community itself and easily accessible, the other a mobile van to conduct the interview and examinations within the participant's neighborhood.]

In the Statement of Work, per part C. Detailed Description of the Technical Requirements, item No. 4:

[Note 2 to Offeror: Additional components of the examination may be proposed and justified, with inclusion of a separate budget.]

In the Statement of Work, per part C. Detailed Description of the Technical Requirements, item No. 4.b.:

[Note 3 to Offeror: The Offeror should propose each questionnaire to be used, along with justification. In the case of recommended questionnaires below, the Offeror may propose the recommended questionnaire, or may propose an alternative if the Offeror prefers. The final decision on questionnaires to be used will be decided by the Steering Committee. A questionnaire may be self-administered or interviewer administered with appropriate justification provided for mode of administration.]

In the Statement of Work, per part C. Detailed Description of the Technical Requirements, item No. 4.c.:

[Note 4 to Offerors: If a Field Center wishes to participate as a Pulmonary Function Reading Center, a Sleep Assessment Reading Center or an ECG Reading Center, they may submit a proposal, however, this is not a requirement for the proposal.]

[Note 5 to Offerors: Provide a separate budget for this recommended cognitive status assessment. Offerors may provide additional or substituted measures with a separate budget.]

[Note 6 to Offerors: A separate budget for the dental examination should be provided.]

[Note 7 to Offerors: A separate budget for the audiometry examination should be provided.]

In the Statement of Work, per part C. Detailed Description of the Technical Requirements, item No. 4.d.:

[Note 8 to Offerors: If a Field Center wishes to be a Central Laboratory, they may respond to that solicitation (to be issued by the study Coordinating Center at a later date) but this is not a requirement for response.]

In the Statement of Work, per part C. Detailed Description of the Technical Requirements, item 9.:

[Note to 9 Offerors: Though the data system will be determined later, for budget purposes, the Field Center should propose a data collection system which it would prefer, and propose a budget accordingly.]

In the Statement of Work, per part C. Detailed Description of the Technical Requirements, item No. 15.:

[Note 10 to Offerors: A Field Center should plan for 5 trips to Bethesda, Maryland in the first year for Steering Committee meetings, and 2 a year thereafter. A Field Center should plan for one trip per year by the PI to Bethesda for the Monitoring Board meetings. A Field Center should plan for a trip to a central training site for all of its staff in the first year and trips for training of new staff throughout the study time period.]

Note 11 to Offerors: Please include the cost breakdown electronically i.e. via CD using the following spreadsheet format" http://www.niaid.nih.gov/contract/forms.htm

SECTION M - EVALUATION FACTORS FOR AWARD

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost/price, and small disadvantaged business (SDB) participation. The technical proposal will receive paramount consideration in the selection of the contractor(s) for this acquisition. Past performance is NOT an evaluation factor but will be considered in determining an offeror's responsibility in accordance with FAR 9.104-3(b). All evaluation factors other than cost or price, when combined, are significantly more important than cost/price. The trade-off process described in FAR 15.101-1 will be employed. This process permits tradeoffs among cost/price and non-cost factors and allows the Government to consider award to other than the lowest priced or highest technically rated offeror. In any event, the Government reserves the right to make an award to that offeror whose proposal provides the best value to the Government.

The Government reserves the right to make an award without further discussion of the proposals received. Therefore, it is important that your proposal be submitted initially on the most favorable terms and should include a detailed budget. Proposals submitted in response to this solicitation will be reviewed by a peer review group.

The RFP does not commit the Government to pay any cost for the preparation and submission of a proposal. In addition, the Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed acquisition.

a. **HUMAN SUBJECT EVALUATION**

This research project involves human subjects. NIH Policy requires:

(a) **Protection of Human Subjects from Research Risks**

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation in the proposed research plan, or provide sufficient information on the research subjects to allow a determination by NHLBI that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the protection of human subjects from research risks is still found to be unacceptable, then your proposal may not be considered further for award.

(b) **Women and Minorities**

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR
- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged), OR
- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants.

Reviewers will consider the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:
    - the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
    - overriding factors dictate selection of subjects); or
    - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.
- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:
    - inclusion of those groups would be inappropriate with respect to their health,;or
    - inclusion of those groups would be inappropriate with respect to the purpose of the research.

- For NIH-defined Phase III clinical trials, reviewers will also consider whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research

Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or "acceptable." See Section L of the solicitation for the requirements of women/minorities inclusion. If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion/exclusion of women and minorities is still found to be unacceptable, then your proposal may not be considered further for award.

(c) **Children**

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are clear and compelling reasons not to include them.

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers' evaluation of the offeror's response, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in accordance wit h NIH policy guidelines) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion of children is still found to be unacceptable, then your proposal may not be considered further for award.

If the information provided in your proposal about the inclusion of children is rated “unacceptable” and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your plan during discussions and in your Final Proposal Revision (FPR). If your plan for inclusion of children is still considered “unacceptable” by the Government after discussions, your proposal may not be considered further for award.

b. EVALUATION OF DATA SHARING PLAN

The offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy.

If your proposal does not include a plan or if the plan in your proposal is considered “unacceptable,” and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your data sharing plan during discussions and in your Final Proposal Revision (FPR). If your data sharing plan is still considered “unacceptable” by the Government after discussions, your proposal may not be considered further for award.

c. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

1. Adequacy and feasibility of the approach for sampling and recruitment of a representative sample of participants, plans to assess risk factors and acculturation, conduct of the study examinations, development and implementation of questionnaires, development and execution of operational procedures, plans for interaction with coordinating center and reading centers, and plans for morbidity and mortality follow-up as outlined in the Statement of Work and in accordance with the study=s objectives. (30 points)

2. Expertise, experience and adequate commitment of professional staff pertinent to study objectives. Key staff must demonstrate productivity in analysis, presentation, and publication of epidemiologic data; and knowledge and expertise in the epidemiology of the following: cardiovascular and lung diseases, sleep and hearing disorders, diabetes, and dental conditions. (30 points)

3. Demonstration of previously successful interaction between the Field Center and the Hispanic community selected for study. Adequacy of plan to provide a return to the community in health education and study results. (15 points)

4. Adequacy of plans to facilitate productive use of data and materials by investigators outside the study, including plans to publicize the availability of limited use data and the ancillary study mechanism and to respond to inquiries regarding them. (10 points)

5. Adequacy of the administrative structure, support staff and institutional support for managing the anticipated volume and variety of data collected. Availability of adequate facilities and equipment, including technical hardware. (15 points)

d. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

(a) Extent to which SDB concerns are specifically identified

(b) Extent of commitment to use SDB concerns

(c) Complexity and variety of the work SDB concerns are to perform

(d) Realism of the proposal

(e) Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation

(f) Extent of participation of SDB concerns in terms of the value of the total acquisition.

SOLICITATION ATTACHMENTS INCLUDED WITH THE RFP

The following pages include Attachments applicable to this RFP as specified in SECTION J - List of Attachments

PACKAGING AND DELIVERY OF THE PROPOSAL

Your proposal shall be organized as specified in Section L.2., "Instructions to Offerors" - General Instructions. Shipment and marking shall be as indicated below.

EXTERNAL PACKAGE MARKING: In addition to the address cited below, mark each package as follows:

"RFP NO. NHLBI-HC-06-02, Hispanic Community Health Study - Field Center
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

NUMBER OF COPIES

TECHNICAL PROPOSAL: ORIGINAL * AND THIRTY-FIVE (35) COPIES
BUSINESS PROPOSAL: ORIGINAL AND SIX (10) TEN

If hand-delivered or delivery service
Review Branch, Division of Extramural Activities
National Heart, Lung, and Blood Institute
Rockledge 2, Room 7091
6701 ROCKLEDGE DR MSC 7924
BETHESDA, MD 20817

If using U.S. Postal Service
Research Branch, Division of Extramural Activities
National Heart, Lung, and Blood Institute
Rockledge 2, Room 7091
ROCKLEDGE DR MSC 7924
BETHESDA, MD 20892-7924

***THE **ORIGINALS** MUST BE READILY ACCESSIBLE FOR DATE STAMPING PURPOSES.

Attachment 2

PROPOSAL INTENT RESPONSE SHEET

RFP No. NHLBI-HC-06-02 (FAX BY NOVEMBER 1, 2005)

TITLE: Hispanic Community Health Study - Field Centers

PLEASE REVIEW THE REQUEST FOR PROPOSAL. FURNISH THE INFORMATION REQUESTED BELOW AND RETURN THIS PAGE BY THE EARLIEST PRACTICABLE DATE. YOUR EXPRESSION OF INTENT IS NOT BINDING BUT WILL GREATLY ASSIST US IN PLANNING FOR PROPOSAL EVALUATION.

[ ] DO INTEND TO SUBMIT A PROPOSAL

[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

COMPANY/INSTITUTION NAME:

ADDRESS:

PROJECT DIRECTOR'S NAME:

TITLE:

TELEPHONE NUMBER:

E-MAIL ADDRESS:

NAMES OF COLLABORATING INSTITUTIONS AND INVESTIGATORS
(include Subcontractors and Consultants):

AUTHORIZED SIGNATURE:

TYPED NAME AND TITLE:

DATE:

RETURN TO:

National Institutes of Health
National Heart, Lung and Blood Institute

Attention: Dr. Valerie Prenger
Bethesda MD 20892-7902
FAX: (301) 480-0730

Save As... Print Clear Form

ATTACHMENT 3

Hispanic Community Health Study

Field Center

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work.

Note: While communities have differing words to express their ethnic identity, throughout this document, we will use the word Hispanic to be inclusive of all Hispanic or Latino groups, that is those who self-identify their origin (either recent or distant past) from Spanish or Portuguese speaking countries of North, Central or South America (including Caribbean Islands), or from Spain or Portugal.

A. General Description of the Required Objectives and Desired Results

The overall objectives of this research are to identify the prevalence of and risk factors (protective or harmful) for diseases, disorders and conditions in Hispanic populations, and to determine the role of acculturation and disparities in their prevalence and development. This study is intended to be broad-based and will address a wide variety of conditions, including heart disease, stroke, asthma, chronic obstructive lung disease, sleep disorders, dental carries and disease, hearing impairment and tinnitus, diabetes, kidney and liver disease, and cognitive impairment. Risk factors to be assessed include (but are not limited to) nutrition, activity, obesity, smoking, blood pressure, blood lipids, acculturation, social and economic disparity, psychosocial factors, occupation, health care access, medication and supplement use, and environmental context. Samples of Hispanics will be selected to be representative of a defined community, will participate in an examination consisting of interviews and procedures and will be followed over time for disease occurrence. This will be achieved through the following specific objectives in an 8-year contract:

1. To identify up to four communities in the US of persons of Hispanic origin (one community majority Mexican-American, one majority Cuban, one majority Puerto Rican, and one majority Central/South American) with stable population and strong community structure and organization. Balance in geographic distribution of communities and countries of origin will be a consideration in the site selection.

2. To identify, sample and recruit up to 4000 persons of Hispanic origin from each of these separate communities for participation in a longitudinal epidemiology study (up to 16,000 persons total, age 18-74).

3. To conduct a detailed interview and examination of these study participants including fasting blood draw, questionnaires, and procedures to capture health behaviors and risk factors for many chronic diseases.

4. To conduct an annual contact, consisting of a brief questionnaire, of these persons following the initial examination.

5. To identify new coronary heart disease, stroke, heart failure, and chronic obstructive lung disease events that have required hospitalization following the initial examination; to identify acute exacerbations of asthma requiring ER care or hospitalization; to review and adjudicate medical information from hospital, physician and other records.

6. To develop innovative hypotheses, perform data analysis, and produce publications from this study.

7. To provide community education and feedback regarding information from the study itself; to provide information to improve the health of the communities in general; and to provide training for minority investigators.

8. To provide opportunities for ancillary studies funded by other mechanisms by establishing collaborations and publicizing the potential for these opportunities.

The above objectives will be achieved through contracts by the National Heart, Lung, and Blood Institute with up to four Field Centers, and one Coordinating Center. The Coordinating Center will provide the services for a Central Laboratory and Reading Centers as needed (and may do so possibly through awarding subcontracts or other funding mechanism to other organizations to perform these services.) Study protocols will be common to all centers and will be directed by a Steering Committee consisting of a representative of each Field Center, the Coordinating Center and the National Heart, Lung, and Blood Institute. Offerors will provide a proposal based on their assessment of the optimal methods, but after award, standardized protocols will be established by the Steering Committee which may be the same or may be different from that proposed by an individual offeror.

[Note: The National Heart, Lung, and Blood Institute (NHLBI) will manage these contracts, but funding has been provided by the NHLBI and the National Cancer Institute, National Institute on Deafness and Other Communication Disorders, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Neurological Disorders and Stroke, and the NIH Office of Dietary Supplements.]

B. Background Information

The Hispanic population is now the largest minority population in the US with a projected three-fold growth by 2050. Hispanics are influenced by factors less commonly found in other US population groups, including changes in diet, activity, community support, working conditions, and health care access, particularly as these changes are associated with immigration from different cultural settings and environments. They are experiencing increasing obesity, higher risks of diabetes, and changes in social and behavioral factors with large potential impact on many major chronic diseases. They consist of population groups originating from multiple geographic areas and founder populations, and with residence in the US for varying lengths of time, ranging from many generations to less than a year. These differing cultural and genetic backgrounds can have a large potential to influence disease risk.

National data show that US Hispanic populations overall have lower coronary heart disease mortality rates than non-Hispanics but have increased prevalence of obesity and

diabetes. Hispanics also have a lower incidence of, and mortality from, cancer (all sites) than blacks or whites. These data also show that some Hispanic groups have high asthma burden, with Puerto Ricans having a 4-fold higher asthma prevalence than Mexican Americans. Disproportionate numbers of Hispanics have fewer economic resources and more may be employed in occupations with exposures that could adversely affect health and increase risk of disease.

If the immigrant Hispanic populations follow the patterns of most other immigrant groups, their risk of chronic diseases associated with US lifestyle and culture is likely to increase. Observational data are needed to assess changes associated with immigration and acculturation to living in the US, identify those most strongly related to disease risk, and determine how best to prevent the risk factor changes which are most harmful to health. Research in differing cultural settings, such as various Hispanic groups with varying periods of residence in the US, can identify differences in risk factor associations not identifiable in more homogenous US populations. If the risk of some diseases, such as CHD or cancer, is actually lower in Hispanics than in non-Hispanics, or the risk of other diseases, such as asthma, obesity or diabetes is higher in some Hispanic subgroups, identification of factors contributing to these differences will be relevant to both Hispanics and non-Hispanics.

Hispanic populations are very much understudied with respect to many diseases. Their projected population growth underscores the need for accurate evaluation of their disease burden and risk. Their disproportionately lower economic status results in significant disparities in health care. Compared to non-Hispanics, Mexican Americans (and for some indices all Hispanics) are half as likely to have their hypertension controlled, more than twice as often report no usual health care, have a greater prevalence of reported fair or poor health, and are twice as likely to have no health insurance. Asthma appears to be a particular problem in some subgroups, and occupational exposures put lower SES Hispanics at higher risk for other lung diseases.

Longitudinal cohort studies in Hispanic populations are needed to understand the development of risk factors and disease in these populations, and to apply the knowledge gained to prevention of disease in the entire US population.

C. Detailed Description of the Technical Requirements

NOTE: SEE SECTION L: BUSINESS PROPOSAL INSTRUCTIONS, Item 10, FOR NOTES TO OFFERORS REGARDING PROPOSAL PREPARATION

Each Field Center will perform the following activities:

1. Identify a community within the 50 United States or District of Columbia with a large enough Hispanic population to be able to recruit up to 4,000 persons of Hispanic origin to participate in a longitudinal epidemiology study. The age range will be 18-74 and will be sampled to obtain 2,500 persons age 45-74, and 1,500 persons age 18-44. The community needs to be stable so that persons can be contacted over time, and possibly examined more than once. The community needs to have community social infrastructure and organization to enable community support and feedback. The community must be at least 51% of persons of one ethnic origin from either Mexico, Cuba, Puerto Rico, or Central/South American, and the population recruited must be all

self-identified as of Hispanic origin. While the study may recruit more than 51% of a single origin, the study should have, if possible, recruitment of at least 20% of one of the other specified Hispanic groups. The primary sampling unit will be the household, and each offeror will designate the sampling within the household to achieve the recruitment goals. The communities sampled by a Field Center need not necessarily be geographically contiguous, but could be combined to achieve the sample size requirements. However, large geographic distances between communities will not be practical to implement. The Field Center needs to propose the most appropriate sampling plan for their community. The resulting participant sample must be broadly representative of that defined community.

2. Recruit the sampled individuals to attend an examination to assess cardiovascular and other disease risk factors, both known and potential. The risk factors of particular interest are described further in the later section on examination questionnaires and procedures. The percent of identified persons (item 1 above) who actually attend the examination must be at a high level to reduce bias from non-response. There will be no exclusion of persons based on existing health status but the following persons should not be recruited: those who plan on moving away in the next 3 years; those who have health problems, disabilities, or mental problems so severe as to prohibit informed consent and actual clinic attendance. Language barriers are not a reason for exclusion as all contact with participants will be done using the appropriate language.

3. Provide a facility to examine the participants**. [See Note 1 to Offeror in Section L.]**

4. Examine and interview the participants within a 4 hour period and include the components listed below. The NHLBI anticipates the combined time for interviews to be approximately 2 hours and the combined time for the procedures to be approximately 2 hours. The following components should be included **[See Note 2 to Offeror in Section L]:**

a. Welcome, basic identifying information and informed consent.

Personal information including a list of all members of the household, age, background origin, years in the U.S. and social security number for mortality follow-up.

Information on household location sufficient for geocoding using GIS.

Contact information including names, addresses, and telephone numbers of 3 other persons who would know of the participant's location.

An informed consent which needs to comply with all required standards.

Adherence to all HIPAA privacy and disclosure requirements which may be required.

Medical release form allowing the study to obtain access to participant's medical records.

b. Questionnaires: health/medical history, acculturation, social/behavioral, occupation, access/utilization of health care, diet (two 24hr recalls, one food

frequency/propensity), smoking, physical activity, sleep habits, medication use, dental care. The components should include the following, and the administration of these questionnaires can be done in a manner most appropriate for efficient clinic operation and valid responses. **[See Note 3 to Offeror in Section L.]**

A health and medical history including information about general health status, and specific information about cardiovascular and lung illnesses, asthma, diabetes and kidney diseases, cancer, sleep disorders, and hearing loss or tinnitus in the past.

A family history of conditions under study such as cardiovascular disease, diabetes, hearing loss, kidney disease, and cancer.

An acculturation questionnaire including information to measure the degree of acculturation to living in the US and adapting to the US culture. This component should include the state of the art methodology regarding assessment of residence history, country of origin, ancestry, immigration, and degree of adaptation to new physical, cultural, social and economic environment.

A social and behavioral questionnaire including information related to family structure, community engagement, affiliation and association with other social structures such as church or social organizations; formal education and training; traditional and/or Hispanic values and behaviors; risk factor behaviors.

An occupational questionnaire including specific occupation and aspects of occupation potentially related to lung and cardiovascular diseases, cancer, and hearing loss.

A questionnaire regarding health care access and utilization including information on health insurance, use of health care facilities, barriers to access, use of visiting health professionals or *promotores*, use of social and community based services.

One 24-hour dietary recall obtained during the examination. Also during the examination, a food frequency/propensity questionnaire will be obtained. No later than 1 month later, another 24-hour dietary recall will be obtained either through a telephone call, or through a direct interview in the home. Questionnaires and nutrient food tables may need to be developed for Hispanic foods. The recall and frequency/propensity questionnaire should follow the current NHANES protocol with the reference found at:

http://www.cdc.gov/nchs/nhanes.htm.

Additionally, the 24-hour recall should include information on dietary supplements and botanicals, both standard and alternative.

A smoking questionnaire including information on past and current cigarette, cigar, pipe and chewing tobacco use; cessation attempts among smokers, including use of medications to assist with quitting; and use of modified harm-reduction tobacco products.

A questionnaire on alcohol consumption including usual intake and drinking patterns.

A questionnaire on physical activity including a history of usual physical activity including work, household, leisure and sport related activity; information on type of transportation.

A questionnaire assessing disability (e.g. resulting in the modified Rankin scale).

A questionnaire regarding history of weight loss and gain.

A questionnaire on sleep including sleep disordered breathing, apnea, restless leg syndrome, number of hours slept, sleepiness during the day.

A questionnaire on medication use including prescription and nonprescription medications, vitamin/dietary supplements and alternative medications taken in the past 2 weeks. The participant will be instructed to bring to the examination site all of these medications for direct recording.

A questionnaire on oral/dental health including access and barriers to care, oral cancer, oral health-related quality of life. The recommended questionnaire from the National Institute of Dental and Craniofacial Research (NIDCR) can be found in the appendix.

A questionnaire on hearing including self-assessment of hearing ability, hearing aid use, tinnitus, occupational and non-occupations noise exposure, hearing protector use, pressure equalization tube use, recent cold/sinus/earache, recent loud noise/music exposure and self-assessment of hearing symmetry. The recommended questionnaire from the National Institute of Deafness and Other Communication Disorders (NIDCD) can be found in the appendix.

A questionnaire on sun exposure, sun-protection behaviors, skin type, and past history of sunburn.

c. Procedures including measurement of blood pressure, anthropometry, and physical activity, as well as spirometry, cost efficient sleep studies, ECG, dental examination and hearing examination, and cognitive status measurement.

Measure blood pressure in the arm using standard epidemiologic procedures (5 minute rest, 3 measures), and using an automated blood pressure device. Separately, measure ankle and arm blood pressure using standardized Doppler procedures.

Measure pulmonary function with established and standardized procedures for spirometry. Following the first spirometric test, participants with impaired function will inhale a bronchodilator followed by a second spirometry test. The pulmonary function test will be read and evaluated by a Pulmonary Function Reading center selected by the Coordinating Center.

Propose a cost-efficient direct assessment of overnight sleep disordered breathing, particularly to assess sleep interruption due to sleep apnea. The sleep assessment test will be read and evaluated by a Sleep Assessment Reading Center selected by the Coordinating Center.

Obtain a standard digital ECG from each participant. The ECG will be read according to standard protocols by an ECG Reading Center selected by the Coordinating Center.

[See Note 4 to Offeror in Section L.]

Conduct anthropometry including weight, standing height, and abdominal girth.

Conduct an assessment of cognitive status. The following tests are recommended: Six-item screener derived from the Mini-Mental Status Examination; CERAD Word List Learning; Category Fluency Subtest of controlled Oral Word Association Test (COWA): Animal naming; Digit symbol substitution test; and Trailmaking A and B**. [See Note 5 to Offeror in Section L.]**

Measure activity levels using activity monitors worn by the participants.

Conduct a dental examination including assessment of medical exclusion, tooth count, functional occlusion/occlusion pairs, coronal caries, restorative materials, root caries, periodontal disease, and recommendations for dental health care. A summary of the recommended protocol from NIDCR is found in the appendix. A detailed protocol is found in the NHANES web site as described in the appendix. It is anticipated that that the examination will be performed by a dental hygienist or equivalent**. [See Note 6 to Offeror in Section L.]**

Conduct an audiometry examination including otoscopy, acoustic immitance and pure tone audiometry. A summary protocol from the NIDCD is found in the appendix. A detailed protocol can be found in the NHANES web site as described in the appendix. **[See Note 7 to Offeror in Section L.]**

d. Blood draw, urine collection, and laboratory measurements including total cholesterol, HDL cholesterol, triglycerides, glucose, insulin, HbA1c, urinary albumin/creatinine, serum cotinine, serum alanine and aspartate aminotransferase concentrations, fasting serum leptin, iron and transferrin, serum creatinine, serology for hepatitis A, B, and C, HCV RNA (on the subset

hepatitis C positive) and transport to and storage at a central location of samples for future use, including buffy coat storage for later DNA extraction.

Perform venipuncture to obtain fasting blood samples for the laboratory analytes described above. The number and type of tubes will be determined by the final protocol. Whole blood, serum, and plasma should be store for possible future hormone, gene and protein expression analyses. Blood will be processed on site as required by protocol and shipped to Central Laboratories as needed.

Conduct a 2 hour oral glucose tolerance test by providing a participant with the currently recommended glucose load after drawing the fasting blood. Two hours later perform another venipuncture for collection of blood for a measurement of glucose.

Collect a spot urine from each participant early upon arrival at the examination site. The urine will be shipped to a Central Laboratory for processing.

Package and ship samples to a Central Laboratory within a time frame specified within the protocol required for each sample.

Collect additional tubes of blood to be used for 5% blind replicate samples.

[See Note 8 to Offeror in Section L.]

5. Pretest and conduct a pilot run through of all study components. Participate in central training and certification of staff. Conduct questionnaires and perform procedures using state-of-the-art quality control procedures including repeat measurements, quantitative evaluation of performance, and retraining and recertification as needed. Site visits by the coordinating center will be conducted annually to assure compliance with study standards.

6. Provide appropriate medical information from the examination back to the participant and/or doctor. This should include alerts which require prompt attention by the participant, as well as standard reports of measurements of value to each person.

7. Contact examined participants annually, either by telephone or in person, and conduct a brief questionnaire. The questionnaire will obtain information on any doctor or hospital visits in the interim, questions on health during the interim, and an update of contact information. The questionnaire will also contain repeated assessment of three of the cognitive status measures recommended at the baseline visit (Six Item Screener, CERAD Word List Learning and COWA-animal naming as described in section 4.b). The interview will also contain a new instrument, the 13-item modified version of the Telephone Interview for Cognitive Status (TICS-M). Consideration should be given to conducting two of the cognitive assessments during the follow-up in alternating years, so as to shorten the interview time. Procedures for retention in the study and recontact must be planned to obtain a high continued response rate.

8. Identify, abstract, review, and validate cardiovascular and lung events (requiring emergency room visit or hospitalization, or based on death information) which occurred in the interim between the baseline exam and each subsequent annual follow-up.

a. Cardiovascular events include myocardial infarction, stroke and heart failure. Lung events include chronic obstructive lung disease and asthma.

b. Identify possible events from the annual follow-up questionnaire which will provide a self-report that a hospitalization or ER visit took place and the self-reported reason for the visit.

c. Abstract information from these records and enter into the study data base.

d. Validate the diagnosis by review of the abstracted information either by computer or a review committee.

e. Identify deaths from information obtained at the annual follow-up and from a review of the vital statistics lists and obituaries from the state in which the community is located. Conduct a match to the National Death Index periodically (Coordinating Center's responsibility).

f. Establish cause of death by obtaining, abstracting, and reviewing all relevant information from next-of-kin, coroner, physician, and hospital.

g. Review the abstracted information and validate the diagnoses using trained and certified clinicians designated from each Field Center (a morbidity and mortality classification committee).

h. Use the Multi-Ethnic Study of Atherosclerosis (MESA) protocol for event ascertainment, review, and validation of events to assure comparability with another significant study. See the following website: http://mesa-nhlbi.org/manuals.aspx#events

Details regarding assessment of cardiovascular events are well described in the MESA protocol. Details of assessment of chronic obstructive pulmonary disease (COPD) and asthma will be determined by the Steering Committee. The primary goals, however, are to obtain incidence of hospitalized COPD and frequency of exacerbations of asthma requiring ER care or hospitalization.

9. Transmit the data collected at the Field Center to the Coordinating Center weekly at a minimum for their editing and processing. Each field site will use data collection instruments and computer systems as agreed to by the Steering Committee and provided by the Coordinating Center. The Coordinating Center will have primary responsibility for data processing and analysis, but data for the full study will also be distributed to each Field Center for analysis under procedures to be determined by the Steering Committee. The data entry systems could range from direct data entry at each Field Center to centralized data entry at the coordinating center**. [See Note 9 to Offeror in Section L.]**

10. Contribute to the analysis, interpretation, presentation and publication of research results from this study.

11. Maintain close connection and cooperation with the community. Provide for community consultation, focus groups, and community interaction in relation to the goals and performance of the study, and for any unusual or sensitive issues such as genetic testing for identification of ancestry. Provide for health education in return to the community. Propose a plan to assess the impact of this education and feed back on study data. This cooperation, feedback and education are essential for successful recruitment and retention in the study.

12. Cooperate in the preparation of a limited access data set (LADS) of data from this study. Limited access data will be released under this study. Limited access data refers to trial or study data, with certain deletions and recoding, that are released to requesting institutions and investigators for specific purposes and with certain restrictions and conditions. Limited access data will be made available to the public in accordance with the draft NHLBI Policy for Distribution of Data (http://www.nhlbi.nih.gov/funding/inits/ladspolicy.doc.). The NHLBI anticipates that this will be in final form by August 1, 2005. All changes to the policy are hereby incorporated by reference without further amendment to the contract.

13. Collaborate with other investigators, with emphasis on Hispanic investigators, in the analysis of data collected under the contract based statement of work.

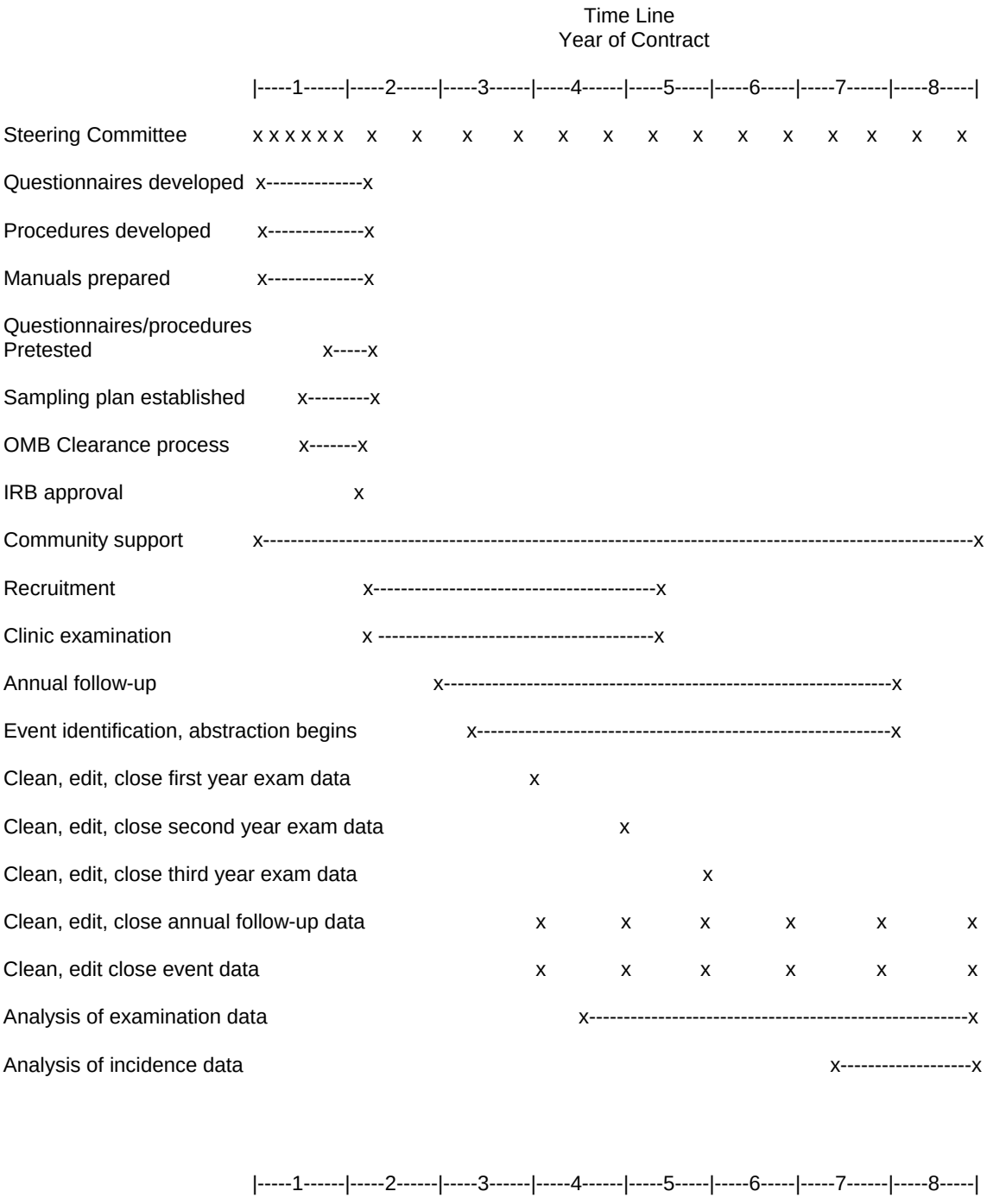
14. Promote the development and implementation of ancillary studies through Federal and non-Federal grant mechanisms, particularly during contract years 5-8 during which there is no regularly scheduled contract required examination. An ancillary study is one which is not required in the statement of work, and not funded under the negotiated contract.

15. Participate in the Steering Committee and in other study committees as needed (e.g., Executive Committee, Exam Committee, Quality Control Committee, Event Committee, Publication Committee). The NHLBI anticipates that it will be necessary for each Field Center to travel to Bethesda, Maryland 5 times in the first year for Steering Committee meetings, and 2 a year thereafter. The NHLBI anticipates that it will be necessary for the Principal Investigator at each Field Center to travel yearly to Bethesda, Maryland for the Monitoring Board meetings. The NHLBI anticipates that it will be necessary for each Field Center to plan for a trip to a central training site for all of its staff in the first year and trips for training of new staff throughout the study time period. **[See Note 10 to Offeror in Section L.]**

16. Provide semiannual reports to the NHLBI regarding study progress, staffing, and finances. Provide raw data or summary data reports to the NHLBI upon request.

E. Phasing

The timeline for the project is listed below.



Specific components for each contract year.

Year 1

Steering committee meets bimonthly and plans and decides on final content.
Questionnaires/instruments are developed for content and cultural specificity.
Procedures are developed, equipment purchased.
Manual of Operations are prepared.
Questionnaires and procedures are pretested.
OMB clearance is obtained.
IRB approval is obtained.
Community support is obtained.
Sampling plan is established.
Web site available for both internal and external use.

Year 2

Recruitment is begun.
Examinations are begun.
Morning examinations to allow for fasting participants.
Approximately 6 participants per day.
Evening and weekend days should be planned for examinations.

Year 3

Recruitment continues
Examinations continue
Data collected in Year 2 are edited, cleaned, and closed out.
Annual contact begins for those examined in Year 2.
Events are identified, medical records obtained, review begun.

Year 4

Recruitment continues and is completed at the end of the year.
Examinations continue and are completed at the end of the year.
Annual follow-up is conducted for those examined in Year 3(1^{st} annual contact), and Year 2 (2^{nd} annual contact).
Data collected in Year 3 edited, cleaned and closed out.
Events are identified, medical records obtained, review continued.

Year 5

Annual follow-up is conducted for those examined in Year 4(1^{st} annual contact), Year 3 (2^{nd} annual contact), and Year 2 (3^{rd} annual contact).
Data collected in Year 4 edited, cleaned and closed out.
Events are identified, medical records obtained, review continued.
Analysis of Exam data begun.

Year 6

Annual follow-up is conducted for those examined in Year 4(2^{nd} annual contact), Year 3 (3^{rd} annual contact), and Year 2 (4^{th} annual contact).
Data collected in Year 5 edited, cleaned and closed out.
Events are identified, medical records obtained, review continued.
Analysis of Exam data continues.

Year 7

Annual follow-up is conducted for those examined in Year 4(3rd annual contact), Year 3 (4th annual contact), and Year 2 (5th annual contact).
Data collected in Year 6 edited, cleaned and closed out.
Events are identified, medical records obtained, review continued.
Analysis of Exam data continues.
Analysis of Incidence data begun.

Year 8

All data edited and closed and delivered to NHLBI.
All paper records stored or destroyed as appropriate.
Permanent specimen storage established and transferred.

Supplemental materials for the RFP – Hispanic Community Health Study

I. MATERIALS RELATED TO THE DENTAL COMPONENT

The Dental examination component will generally follow the procedures which were used in NHANES IV and described in the NHANES 2001 examiners manual. This manual can be found in the following web site:
http://www.cdc.gov/nchs/data/nhanes/oh-e.pdf

A. Examination components

Medical exclusion –as described in the NHANES 2001 Examiners Manual.
Tooth count–as described in the NHANES 2001 Examiners Manual.
Functional Occlusal Contacts Index – The description below is from the NHANES 2004 Examiners Manual. Note the incisal opening element described in the 2004 manual will not be done. The 2004 manual also contains a number of additional examples.
Coronal caries –as described in the NHANES 2001 Examiners Manual.
Restorative materials – described below.
Root caries –as described in the NHANES 2001 Examiners Manual.
Periodontal disease–as described in the NHANES 2001 Examiners Manual with 3 probing sites per tooth (mesial facial, distal facial l, and mid facial) using 1 randomly selected maxillary and 1 randomly selected mandibular quadrant. This component is described in greater detail in the NHANES 2004 Examiners Manual.
Recommendations for dental care –as described in the NHANES 2001 Examiners Manual.

Questions
Quality of life – described below
Access to care– described below
Barriers to care/unmet needs – described below
Oral Cancer – described below

1. The following Simplifications to the Tooth Count and Coronal Caries Examination Codes used in NHANES IV will be made.

Tooth Count:
Primary tooth (deciduous)
Permanent tooth
Implant
Not present
Permanent root tip is present

Coronal Caries:
Missing-**Add**
Missing due to other causes –**Do not use**
Missing due to dental disease –**Do not use**
Primary tooth with surface condition (s)
Missing but replaced by a removable restoration –**Add**
Missing but replaced by a fixed restoration –**Add**

Missing due to dental disease but replaced by a removable restoration – **Do not use**
Missing due to other causes but replaced by a removable restoration –**Do not use**
Missing due to dental disease but replaced by a fixed restoration – **Do not use**
Missing due to other causes, but replaced by a fixed restoration – **Do not use**
Permanent root tip is present but no restorative replacement is present – **Do not use**
Permanent root tip is present and a restorative replacement is present – **Do not use**
Sound permanent tooth
Unerupted
Tooth present, condition cannot be assessed
Permanent tooth with surface condition (s)

Coronal Caries: Surface condition (anterior)
Lingual surface caries
Facial surface caries
Mesial surface caries
Distal surface caries
Lingual surface restoration
Facial surface restoration
Mesial restoration
Distal restoration

Coronal Caries: Surface condition (posterior)
Lingual surface caries
Occlusal caries
Facial surface caries
Mesial caries
Distal caries
Lingual surface restoration
Occlusal restoration
Facial surface restoration
Mesial restoration
Distal restoration

2. Restorative materials Component:

Objective
This component identifies specific restorative materials noted in the oral health examination. They will be counted as amalgam, resin, gold, other, and full coverage crowns.

Methods

The examination will be visual and tactile (an explorer will be used if needed), with one score per restored tooth.

The amalgam category will include restorations composed of any type of amalgam.
The resin category will include all types of composites and resins.
The gold category will include gold inlays, onlays, gold foils, or partial crowns.
The other category will include anything other than an amalgam or composite or gold, such as porcelain onlays, inlays, or glass ionomer restorations when they can be distinguished from composites.

The crown category will include full coverage crowns made of any material (including gold, stainless steal, porcelain, and porcelain fused to metal).

If a restored surface contains more than one type of material the selected material category will be based on the material with the greatest coverage of tooth surface.

3. Functional Occlusal Contacts Index (FOCI)

National epidemiological surveys conducted in the United States have historically focused on descriptions of the oral craniofacial complex largely from a disease perspective by quantifying such conditions as carious lesions, periodontal attachment loss, and oral mucosal pathologies. This supplement to the NHANES dental examination component would further enhance the dentition examination by adding a count of the numbers of functional occlusal contacts of teeth as quantified by an index of the same name (FOCI). The functional occlusal contacts supplement would respond to the need that dental researchers have identified for assessments that more fully describe the functional capacities of the dentition. Having a greater understanding of this feature of the functional capacity of the oral craniofacial complex is of importance to research related to the relationship of oral health status and general health, e.g., diet and nutritional status to health services research. It is integral to answering questions regarding the impact of dental status on oral health-related quality of life.

Description

The dental examiner performs the exam with a surface-reflecting mirror.

This exam will count the number of functional occlusal contacts in such a way to quantify an important aspect of the functional status of the dentition that simple counts of teeth and prostheses alone cannot provide. This is a visual examination that goes beyond counting the number of teeth to count how many of the teeth oppose each other and can function properly when eating.

Description of Index and Scoring System

For the purposes of this examination the participant closes together normally on the back teeth. Using a mouth mirror to hold back the cheek, the examiner looks at the lower arch from the side and records the distribution of contacts. If a

contact is present for a natural tooth to natural tooth contact, code “1” is called. If a contact is present for a natural tooth to a fixed prosthesis or between two fixed prostheses is present, a code “1” is also called. For purposes of this assessment, a code of “1” is reflective of “tooth-borne” contacts. If a contact is present for a natural tooth or a fixed prosthesis and a removable prosthesis, a code “2” is called. If a contact between two removable prostheses is present, a code “3” is called. If however there is no contact, a code “0” (zero) is called.

Methods and Scoring System

The Functional Occlusal Contacts Index (FOCI) consists of (1) an assessment of the posterior (premolar and molar) regions, and then (2) a similar assessment for the sum of anterior tooth contacts. The right and then left posterior regions are assessed for (1) the number of contacts between natural teeth, (2) natural teeth and pontics of fixed prostheses, (3) natural teeth and removable prostheses, and (4) the number of contacts between denture teeth. As there are few anterior teeth missing without prostheses in the U.S. adult population, the anterior assessment is limited to a single assessment requiring at least one anterior mandibular tooth in contact with an opposing anterior tooth irrespective of the type of teeth involved.

A contact is the same as an occlusal stop. For the purposes of this examination, the SP closes together normally on the back teeth. Using a mouth mirror to hold back the cheek, the examiner looks at the lower arch from the side and records the distribution of contacts. In a complete quadrant, there will be 8 possible zones of contact in the posterior region (see diagrams in Section 4.14.4). Each of the premolars is a single zone, and each of the molars is about twice as wide, so they are counted as two zones each.

Codes and Criteria of Occlusal Contact Zones

Posterior functional occlusal contact zones:

0 = No posterior functional contact

1 = “Tooth-borne” functional contact present

2 = Functional contact present between a natural tooth or a fixed prosthesis and a removable prosthesis

3 = Functional contact between two removable prostheses

9 = Cannot assess

Anterior functional occlusal contact zone:

0 = No anterior functional contact

1 = “Tooth-borne” functional contact present

2 = Functional contact present between a natural tooth or a fixed prosthesis and a removable prosthesis

3 = Functional contact between two removable prostheses

9= Cannot assess

Examination Procedures

Scoring begins with the right side, distal to the canine, and counting the number of occlusal contacts distally. The left posterior region is scored next. If a contact is present for a natural tooth to natural tooth contact, a code “1” is called. If a contact is present for a natural tooth to a fixed prosthesis or between two fixed prostheses, a code “I” is also called. If a contact is present for a natural tooth or a fixed prostheses and a removable prosthesis, a code “2” is called. If a contact between two removable prostheses is present, a code “3” is called. If however there is no contact, a code “0” (zero) is called. The calls are made irrespective of which teeth are in contact. For example, if a first premolar has been lost and the second premolar has moved forward, the mesial cusp of the first molar may have taken up the second premolar position, and the second premolar may have taken the first premolar position. However, although it is the second premolar and the first molar that are making the contacts, the contacts will be scored as being in the zones that (in a full dentition) would be occupied by the first and second premolars. Several examples are provided in Section 4.14.4.

For the assessment of anterior contacts, the examiner looks at the six lower anterior teeth and selects the one mandibular incisor and its opposing maxillary anterior tooth (either incisor or canine) that represents the following hierarchical relationship:

I “Tooth-borne” functional contact present

2 = Functional contact present between a natural tooth or a fixed prosthesis and a removable prosthesis

3 = Functional contact between two removable prostheses

0 No anterior functional contact

When people have a deep overbite, they may have difficulty in protrusively producing a true “end-to-end” contact. If so, then it may be difficult to observe a contact even in a more centric relation. Nevertheless, the assumption should be made that a contact exists. Where there is severe anterior open bite, or where lower teeth are missing, there clearly cannot be a contact. Nevertheless, an attempt should be made to assess for the potential of a functional occlusal contact in an anterior open bite condition.

Scoring Guidelines

• A posterior functional contact is classified as present where the contact form a vertical occlusal stop. This is recorded according to the lower even if the area of contact is small. In rare cases where there is contact but no occlusal stop (e.g., a scissors bite), a zero is recorded. Clearly there can be no contact if there is no lower tooth in the zone.

• In some cases it may be difficult to tell whether the teeth actually touch or not; if in doubt, the assumption should be made that the contact is present.

• Where there are small spaces in the lower arch and you cannot decide whether you should consider it as a whole zone, count the space as a full zone if the space is wider than a half a tooth; otherwise ignore it.

• Removable prosthesis contact must be a contact involving a denture tooth and not contact to an acrylic base plate alone.

• If contact is observed involving gross cavitation and caries, this type of contact is not considered to be “functional” and should be coded as “0.”

• If the SP presents with having left his/her removable denture(s) at home, the examiner cannot assess for functional contacts and the code of “9” should be used where appropriate.

Examples of Scoring Functional Occlusal Contacts

Examples of Scoring Contacts

Figure 1

Right side:
Several lower teeth are present but do not make contact, and the two molars have drifted forward into the distal half of the space where the first molar was. Starting distal to the canine and working back the call for all natural teeth would be

0.0.0.1.1. 0.1.0

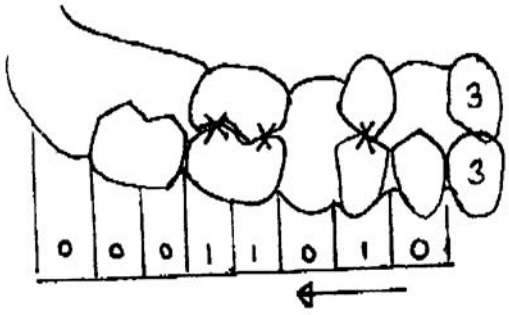


Figure 2

Left side: On this side there has been a fair amount of drifting, but this isn’t relevant to the numbers of functional occlusal contacts. The calls from the distal of the canine towards the distal of the left side of the mouth are

0.0.1.1.1.0.0.0

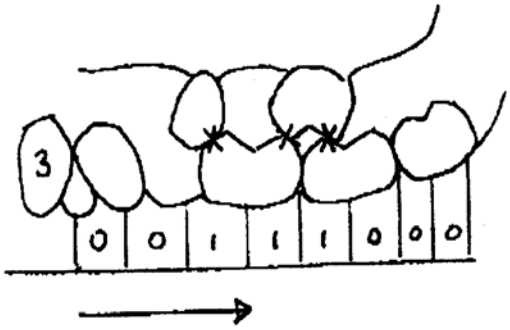
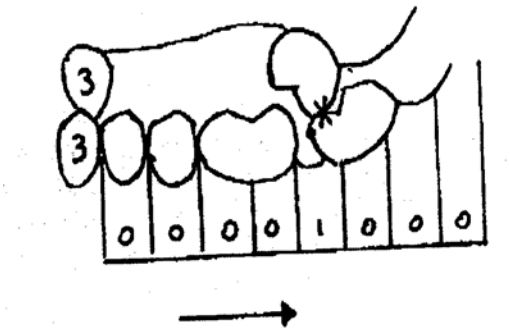


Figure 3

Left side: All but one maxillary tooth has been lost and the one remaining tooth has drifted and tipped forward and makes a contact in about the fifth zone back (roughly where the mesial half of the second molar would be. Sometimes this position can be difficult to judge accurately. Whether the contact is actually in that position or one zone, either side is not critical, what is important is that it is in the middle of the molar region. The calls are

0.0.0.0.1.0.0.0



B. Questions to ask study participants.

1. Barriers to care/unmet needs questions –

I have some questions about your mouth and teeth.

Q1. How would you describe the condition of your mouth and teeth? Would you say . INCLUDE FALSE TEETH AND DENTURES
1 Very good,
2 Good,
3 Fair, or
4 Poor?
7 Refused
9 Don't know

Q2. How often do you limit the kinds or amounts of food you eat because of problems with your teeth or dentures? Would you say . . .
1 Always,
2 Very often,
3 Often,
4 Sometimes,
5 Seldom,
6 Never?
77 Refused
99 Don't know

Q3. During the past 12 months, was there a time when you needed dental care but could not get it at that time?

1 Yes
2 No
3 DK/don't remember

If Yes ask:

Q.4
The last time you could not get the dental care (you/he/she) needed, what was the main reason you couldn't get care?

1 Could not afford it
2 No insurance
3 Dentist did not accept Medicaid/insurance
4 Not serious enough
5 Wait too long in clinic/office
6 Difficulty in getting appointment
7 Don't like/trust/believe in dentists/ afraid/ Needles
8 No dentist available
9 Didn't know where to go
10 No way to get there
11 Hours not convenient
12 Speak a different language
13 Health of another family member
14 Could not get time off from work
15 Other reason
16 DK/don't remember

Q5. Do you think or believe that you are currently in need of dental treatment?

1 Yes
2 No

If Yes ask:

Q6. What type of dental care do you need now? (check all that apply)

1 Teeth filled or replaced (for example, fillings, crowns, and/or bridges)
2 Teeth pulled
3 Gum treatment
4 Denture work
5 Relief of pain
6 Work to improve appearance (for example, braces, bonding, or whitening)
7 Cleaning or checkup
8 Other, specify):
0 Nothing
99 DK

2. Access to Dental Care Questions

Q7. About how long has it been since you last visited a dentist? Include all types of dentists, such as, orthodontists, oral surgeons, and all other dental specialists, as well as dental hygienists.

1= 6 months or less
2= More than 6 months, but not more than 1 year ago
3= More than 1 year, but not more than 2 years ago
4= More than 2 years, but not more than 3 years ago
5= More than 3 years, but not more than 5 years ago
6= More than 5 years ago
7= Never have been
77= Refused
99= Don't know

If no visit within the past year ask:

Q. 8 What are the reasons you have not visited the dentist in over 12 months/never gone to the dentist?

1 Afraid
2 Nervous
3 Needles
4 Cost
5 DK dentist
6 Dentist too far
7 Can’t find a dentist who speaks Spanish
8 Can't get there
9 No problems
10 No teeth
11 Not important
12 Didn't think of it
88 Other (specify):
99 DK

If ever had a dental visit ask:

Q9. What was the main reason you last visited the dentist?

1 Went in on own for check-up, examination, or cleaning
2 Was called in by the dentist for check-up, examination
3 Something was wrong, bothering or hurting me
4 Went for treatment of a condition that dentist discovered
5 Other
7 Refused
9 Don't know

If ever had a dental visit ask:

Q10. Is there a particular dentist or dental clinic that you usually go to if you need dental care or dental advice?

1 Yes
2 No
7 Refused
9 Don't know

If ever had a dental visit ask:

Q11. For this last visit, how long was it from the time you decided you needed or wanted to see a dentist until you actually saw him?

1 Less than one day
2 1-6 days
3 1 week but less than 2 weeks
4 2-3 weeks
5 1-2 months
6 3 months or more
9 Don't remember

Q12. Was this wait longer than you would have liked it?

1 Yes
2 No
9 Don't remember

Q13. How well satisfied were you with this visit?

1 Satisfied
2 Not completely satisfied
3 Dissatisfied
4 No opinion
9 DK

3. Oral Health Related Quality of Life Questions.

Q14. During the past month, have you had painful aching anywhere in your mouth?

Q15. During the past month, have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?

Q16. During the past month, have you had difficulty doing your usual jobs or attending school because of problems with your teeth, mouth or dentures?

Q17. During the past month has your sense of taste been affected by problems with your teeth, mouth or dentures?

Q18. During the past month, have you avoided particular foods because of problems with your teeth, mouth or dentures?

Q19. During the past month, have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?

Q20. During the past month, have you been self-conscious or embarrassed because of your teeth, mouth or dentures?

Responses: 1 = yes, 2 = no, 9 = can’t respond

4. Oral Cancer

Q21. Have you ever had a test for oral cancer in which the doctor or dentist pulls on your tongue, sometimes with a gauge wrapped around it, and feels under the tongue and inside the cheeks?

0 I think so
1 Yes
2 No
7 Refused
9 DK, not sure

If ever had an oral cancer exam ask:

Q22. When did you have your most recent oral cancer exam? Was it within the past year, between 1 and 3 years ago, or over 3 years ago?

1 Within the past year
2 1 to 3 years ago
3 Over 3 years ago
99 DK

Supplemental materials for the RFP – Hispanic Community Health Study

II. MATERIALS RELATED TO THE HEARING COMPONENT

The references which follow regarding NHANES can be found in the following web site: http://www.cdc.gov/nchs/about/major/nhanes/nhanes01-02.htm

A. Examination procedures

The NHANES audiometry protocol is available at:

http://www.cdc.gov/nchs/data/nhanes/au.pdf

Otoscopy

Participants will receive a brief visual examination of the ear, primarily to assure a clear sound path. In addition, the technician will check for potential collapsing ear canals and presence of excessive cerumen, which would prevent use of insert earphones, and any other significant abnormality.

Acoustic Immittance

An automated acoustic immittance test battery will be performed that includes tympanometry and a screening (105 dB) for ipsilateral acoustic reflexes at 1000 and 2000 Hz bilaterally. Technicians will evaluate the adequacy of the tympanogram (on the basis of smoothness, symmetry, etc.) and retest if necessary. Interpretation of the tympanograms and reflexes will be done later by a trained audiologist.

Pure Tone Audiometry

Pure tone air conduction thresholds will be obtained bilaterally at 500, 1000, 2000, 3000, 4000, 6000, and 8000 Hz. A retest threshold is obtained in both ears at 1000 Hz as a measure of test reliability. The thresholds are generally obtained automatically through a microprocessor-based audiometer; although the technicians are trained to conduct manual testing as necessary. The first test ear is alternated, except when there is a reported difference between ears, in which case the test begins in the better ear.

In cases where there is a significant inter-ear difference (25 dB or greater at 500 and 1000 Hz, or 40 dB or greater at the remaining frequencies), thresholds are retested using insert earphones to maximize inter-aural attenuation. The audiometer stores separate calibration levels for standard and insert earphones, so no conversions are necessary between phones.

B. Questionnaire components

Recommended questions can be found in the NHANES protocol at the following website:
http://www.cdc.gov/nchs/data/nhanes/nhanes_01_02/sp_auq.pdf

Survey participants will take part in an extensive interview prior to their examination (follow-up interviews will also be conducted annually for five years following the examination). The interview will include questions on the following topics relevant to the audiometry component:

Self-assessment of hearing ability
Hearing aid use
Tinnitus
Occupational history and noise exposure
Exposure to non-occupational noise
Hearing protector use

Additionally, just prior to the hearing test, participants are asked additional questions about conditions that could affect how the test is conducted or interpreted. These questions inquire about:

Pressure equalization tubes
Cold, sinus problem, or earache within the 24 hours preceding the test
Exposure to loud noise or music under headphones in the 24 hours preceding the test
Self-assessment of hearing symmetry

Sample Occupational History Questions extracted from NHANES IV (1999-2004):

OCQ.300 In this job, {do you/does SP} **ever** wear protective equipment?

YES 1
NO 2 (OCQ.340)
REFUSED 7 (OCQ.340)
DON'T KNOW 9 (OCQ.340)

OCQ.310 {Do you/Does SP} **ever** wear . . .
RESPONSES: YES = 1, NO = 2, REFUSED = 7, DON'T KNOW = 9

a. a respirator? ____
b. protective hearing devices? ____
c. protective gloves other than those for cold weather (protective gloves include special gloves to protect your hands against chemicals, cuts, tears, punctures, heat, flame, subzero cold, biological or body fluids)? ____

OCQ.340 Thinking of all the jobs {you have/SP has} **ever** had, {have you/has s/he} **ever** been exposed to loud noise at work for at least **three months**? By loud noise I mean noise so loud that {you/s/he} had to speak in a raised voice to be heard?

YES 1
NO 2 (OCQ.390)
REFUSED 7 (OCQ.390)

DON'T KNOW 9 (OCQ.390)

OCQ.350 At {your/SP's} job as a(n) {OCCUPATION} for {EMPLOYER}, {are you/is s/he} **currently** exposed to loud noise? [By loud noise I mean noise so loud that {you/s/he} {have/has} to speak in a raised voice to beheard?]

YES 1
NO 2 (OCQ.390)
REFUSED 7 (OCQ.390)
DON'T KNOW 9 (OCQ.390)

OCQ.360 On average, for how many hours **per day** {are you/is SP} **currently** exposed to this loud noise?

IF LESS THAN 1 HOUR, ENTER 1 |___|___|
ENTER NUMBER OF HOURS
REFUSED 77
DON'T KNOW 99

OCQ.420 Thinking of all the previous jobs {you have/SP has} **ever** had, {have you/has s/he} **ever** been exposed to loud noise at work for at least **three months**? [By loud noise I mean noise so loud that {you/s/he} had to speak in a raised voice to be heard?]

YES 1
NO . . . . . 2 (BOX 5)
REFUSED . . . . . 7 (BOX 5)
DON'T KNOW . . . . . 9 (BOX 5)

OCQ.430 Remembering the kind of work {you/SP} did the longest, that is, as a(n) {KIND OF WORK DOING THE LONGEST}, {were you/was s/he} **ever** exposed to loud noise in that job for at least **three months**? [By loud noise I mean noise so loud that {you/s/he} had to speak in a raised voice to be heard?]

YES 1
NO . . . . . 2 (BOX 5)
REFUSED . . . . . 7 (BOX 5)
DON'T KNOW . . . . . 9 (BOX 5)

OCQ.440 On average, for how many hours **per day** {were you/was SP} exposed to loud noise in that job?

IF LESS THAN 1 HOUR, ENTER 1
|___|___|
ENTER NUMBER OF HOURS
REFUSED 77
DON'T KNOW 99

OCQ.450 Did {you/SP} **ever** wear protective hearing devices while {you were/s/he was} exposed to loud noise in that job?

YES 1
NO 2
REFUSED 7

DON'T KNOW 9